IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-924-CFC
	)	
AMGEN INC.,	)	
	)	
Defendant.	)	
	)	

PROPOSED JOINT FINAL JURY INSTRUCTIONS

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1. GENERAL INSTRUCTIONS[1]

1.1 INTRODUCTION

Members of the jury, now it is time for me to instruct you about the law that you must follow in deciding this case.

I will start by explaining your duties and the general rules that apply in every civil case. Then I will explain some rules that you must use in evaluating particular testimony and evidence. Then I will explain the positions of the parties and the law you will apply in this case. Finally, I will explain the rules that you must follow during your deliberations in the jury room, and the possible verdicts you may return.

Please listen very carefully to everything I say. In following my instructions you must follow all of them and not single out some and ignore others. They are all important.

You will have a written copy of these instructions with you in the jury room for your reference during your deliberations. You will also have a verdict form, which will list the questions that you must answer to decide this case.

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[1] The parties reserve their rights to propose further amendments to these proposed jury instructions consistent with legal issues that may arise after the filing of these proposed instructions.

Authority:

Orexo AB v. Actavis Elizabeth, LLC, C.A. No. 1:17-cv-00205-CFC, D.I. 240, Proposed Joint Final Jury Instructions (D. Del. March 28, 2019) at 1-2; *Amgen v. Hospira*, C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. Sept. 22, 2017) at 1; *E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No. 1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 1; *AVM Tech., LLC v. Intel Corp*., C.A. No. 15-33-RGA-MPT, D.I. 719, Final Jury Instructions (D. Del. May 8, 2017) at 1; *EMC Corp. v. Pure Storage, Inc*., C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 1.

1.2 JURORS' DUTIES

You have two main duties as jurors. The first one is to decide what the facts are from the evidence that you saw and heard here in court. Deciding what the facts are is your job, not mine, and nothing that I have said or done during this trial was meant to influence your decision about the facts in any way. Your second duty is to take the law that I give you, apply it to the facts, and decide, under the appropriate burden of proof, which party should prevail on each of the issues presented.

It is my job to instruct you about the law, and you are bound by the oath that you took at the beginning of the trial to follow the instructions that I give you, even if you personally disagree with them. This includes the instructions that I gave you before and during the trial, and these instructions. All of the instructions are important, and you should consider them together as a whole.

Perform these duties fairly. Do not let any bias, sympathy or prejudice that you may feel

toward one side or the other influence your decision in any way.

Authority:

Orexo AB v. Actavis Elizabeth, LLC, No. 1:17-cv-00205-CFC, D.I. 240, Proposed Joint Final Jury Instructions (D. Del. March 28, 2019) at 1-2; *Amgen v. Hospira,*

C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. Sept. 22, 2017) at 2; E.I. *DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No. 1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 2; *AVM Tech., LLC v. Intel Corp.*, C.A. No. 15-33-RGA-MPT, D.I. 719, Final Jury Instructions (D. Del. May 8, 2017) at 2; *EMC Corp. v. Pure Storage, Inc.*, C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 2.

1.3 EVIDENCE DEFINED

You must make your decision based only on the evidence that you saw and heard here in court. Do not let rumors, suspicions, or anything else that you may have seen or heard outside of court influence your decision in any way. You should consider all of the evidence, no matter what form it takes, and no matter which party introduced it.

The evidence in this case includes only what the witnesses said while they were testifying under oath, deposition testimony that was presented to you, the exhibits that I allowed into evidence, the stipulations that the lawyers agreed to, and any other evidence that I have judicially noticed.

Nothing else is evidence. The lawyers' statements and arguments are not evidence. The arguments of the lawyers are offered solely as an aid to help you in your determination of the facts. Their questions and objections are not evidence. My legal rulings are not evidence. My comments and questions are not evidence.

During the trial I may have not let you hear the answers to some of the questions that the lawyers asked. I also may have ruled that you could not see some of the exhibits that the lawyers wanted you to see. And sometimes I may have ordered you to disregard things that you saw or heard, or I struck things from the record. You must completely ignore all of these things. Do not even think about them. Do not speculate about what a witness might have said or what an

exhibit might have shown. These things are not evidence, and you are bound by your oath not to let them influence your decision in any way. Sometimes testimony and exhibits are received only for a limited purpose. When I give instructions regarding that limited purpose, you must follow it.

Make your decision based only on the evidence, as I have defined it here, and nothing else.

Authority:

Orexo AB v. Actavis Elizabeth, LLC, C.A. No. 1:17-cv-00205-CFC, D.I. 240, Proposed Joint Final Jury Instructions (D. Del. March 28, 2019) at 3; *Amgen v. Hospira*, C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. Sept. 22, 2017) at 3; *E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No. 1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 4; *AVM Tech., LLC v. Intel Corp*., C.A. No. 15-33-RGA-MPT, D.I. 719, Final Jury Instructions (D. Del. May 8, 2017) at 4; *EMC Corp. v. Pure Storage, Inc*., C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 4.

1.4 CONSIDERATION OF EVIDENCE

You should use your common sense in weighing the evidence. Consider the evidence in light of your everyday experience with people and events and give it whatever weight you believe it deserves. If your experience tells you that certain evidence reasonably leads to a conclusion, you are free to reach that conclusion.

Authority:

Amgen v. Hospira, C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. Sept. 22, 2017) at 4*; E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No. 1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 5; *AVM Tech., LLC v. Intel Corp*., C.A. No. 15-33-RGA-MPT, D.I. 719, Final Jury Instructions (D. Del. May 8, 2017) at 7; *EMC Corp. v. Pure Storage, Inc*., C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 5.

1.5 DIRECT AND CIRCUMSTANTIAL EVIDENCE

There are two kinds of evidence: direct evidence and circumstantial evidence.

Direct evidence is direct proof of a fact, such as the testimony of an eyewitness. For example, if a witness testified that she saw it raining outside, and you believed her, that would be direct evidence that it was raining.

Circumstantial evidence is indirect proof of a fact, that is, proof of facts from which you may infer or conclude that other facts exist. For example, if someone walked into the courtroom wearing a raincoat covered with drops of water and carrying a wet umbrella, that would be circumstantial evidence from which you could conclude that it was raining.

The law makes no distinction between the weight that you should give to either direct or circumstantial evidence, nor does it say that one type of evidence is any better evidence than the other. You should consider all of the evidence, both direct and circumstantial, and give it whatever weight you believe it deserves.

Authority:

Orexo AB v. Actavis Elizabeth, LLC, C.A. No. 1:17-cv-00205-CFC, D.I. 240, Proposed Joint Final Jury Instructions (D. Del. March 28, 2019) at 4; *Amgen v.*

Hospira, C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. Sept. 22, 2017) at 5; *E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No. 1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 6; *EMC Corp. v. Pure Storage, Inc*., C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 6.

1.6 CREDIBILITY OF WITNESSES

You are the sole judges of each witness's credibility. You should consider each witness's means of knowledge; strength of memory; and opportunity to observe; how reasonable or unreasonable the testimony is; whether it is consistent or inconsistent; and whether it has been contradicted; the witness's biases, prejudices, or interests; the witness's manner or demeanor on the witness stand; and all circumstances that, according to the evidence, could affect the credibility of the testimony.

If you find the testimony to be contradictory, you must try to reconcile it, if reasonably possible, so as to make one harmonious story of it all. But if you cannot do this, then it is your duty and privilege to believe the portions of testimony that, in your judgment, are most believable and disregard any testimony that, in your judgment, is not believable.

In determining the weight to give to the testimony of a witness, you should ask yourself whether there was evidence tending to prove that the witness testified falsely about some important fact, or, whether there was evidence that at some other time the witness said or did something, or failed to say or do something, that was different from the testimony he or she gave at the trial. You have the right to distrust such witness's testimony in other particulars and you may reject all or

some of the testimony of that witness or give it such credibility as you may think it deserves.

You should remember that a simple mistake by a witness does not necessarily mean that the witness was not telling the truth. People may tend to forget some things or remember other things inaccurately. If a witness has made a misstatement, you must consider whether it was simply an innocent lapse of memory or an intentional falsehood, and that may depend on whether it concerns an important fact or an unimportant detail.

This instruction applies to all witnesses, including expert witnesses and witnesses who

provided testimony by deposition.

Authority:

Orexo AB v. Actavis Elizabeth, LLC, C.A. No. 1:17-cv-00205-CFC, D.I. 240, Proposed Joint Final Jury Instructions (D. Del. March 28, 2019) at 8; *Amgen v. Hospira*, C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. Sept. 22, 2017) at 6*; E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No. 1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 7-8; *EMC Corp. v. Pure Storage, Inc.*, C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 7-8.

1.7 DEPOSITION TESTIMONY

A deposition is the sworn testimony of a witness taken before trial. The witness is placed under oath and swears to tell the truth, and lawyers for each party may ask questions. A court reporter is present and records the questions and answers. The deposition may also be recorded on videotape.

During the trial, certain testimony was presented to you through depositions that were electronically played or read into the record. You should not attribute any significance to the fact that the deposition is played by video or read by other people. This testimony may have been edited or cut to exclude irrelevant testimony. You should not attribute any significance to the fact that the videos or the read excerpts may appear to have been edited. This testimony must be given the same consideration you would give it had the witness personally appeared in court. Like the testimony of a live witness, the statements made in a deposition are made under oath and are considered evidence that may be used to prove particular facts.

Authority:

Orexo AB v. Actavis Elizabeth, LLC, C.A. No. 1:17-cv-00205-CFC, D.I. 240, Proposed Joint Final Jury Instructions (D. Del. March 28, 2019) at 11; *Amgen v.*

Hospira, C.A. No. 1:15-cv-839-RGA, D.I. 300, Proposed Jury Instructions (D. Del. Sept. 7, 2017) at 9.

1.8 EXPERT WITNESSES

During the trial, you heard testimony from expert witnesses. When knowledge of technical subject matter may be helpful to the jury, a person who has special training or experience in that technical field—called an expert witness—is permitted to state his or her opinion on those technical matters. This skill or knowledge is not common to the average person but has been acquired by the expert through special study or experience.

In weighing expert testimony, you may consider the expert's qualifications, the reasons for the expert's opinions, and the reliability of the information supporting the expert's opinions, as well as the factors I have previously mentioned for weighing testimony of any other witness. Expert testimony should receive whatever weight and credit you think appropriate, given all the other evidence in the case. You are free to accept or reject the testimony of experts, just as with any other witness.

Authority:

Orexo AB v. Actavis Elizabeth, LLC, C.A. No. 1:17-cv-00205-CFC, D.I. 240, Proposed Joint Final Jury Instructions (D. Del. March 28, 2019) at 9; *Amgen v. Hospira*, C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. Sept. 22, 2017) at 7; *E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No.

1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 10; *EMC Corp. v. Pure Storage, Inc*., C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 10.

1.9 NUMBER OF WITNESSES

One more point about the witnesses. Sometimes jurors wonder if the number of witnesses who testified makes any difference.

Do not make any decisions based only on the number of witnesses who testified. What is more important is how believable the witnesses were, and how much weight you think their testimony deserves. Concentrate on that, not the numbers.

Authority:

Orexo AB v. Actavis Elizabeth, LLC, C.A. No. 1:17-cv-00205-CFC, D.I. 240, Proposed Joint Final Jury Instructions (D. Del. March 28, 2019) at 10; *Amgen v. Hospira*, C.A. No. 1:15-cv-839-RGA, D.I. 300, Proposed Jury Instructions (D. Del. Sept. 7, 2017) at 8; *E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No. 1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 9; *EMC Corp. v. Pure Storage, Inc*., C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 9.

1.10 STIPULATION

A stipulation is a fact that the parties have agreed on, and the parties' stipulated facts have been read to you during this trial. You must therefore treat these stipulated facts as having been proved for the purposes of this case.

Authority:

Amgen v. Hospira, C.A. No. 1:15-cv-839-RGA, D. I. 300, Proposed Jury Instructions (D. Del. Sept. 7, 2017) at 11; Third Circuit Model Jury § 2.4 (Oct. 2017) at 26.

1.11 EXHIBITS AND DEMONSTRATIVE EXHIBITS

During the course of the trial, you have seen many exhibits. Many of these exhibits were admitted as evidence. Some of these admitted exhibits or portions of them have been displayed for you on a screen and you will have these admitted exhibits, whether displayed on a screen or not, in the jury room for your deliberations.

There are other exhibits (including charts and animations presented by attorneys and witnesses) that were offered to help illustrate the testimony of the various witnesses. These illustrations, called "demonstrative exhibits," have not been admitted as evidence, are not evidence, and should not be considered as evidence. Rather, it is the underlying testimony of the witness that you heard when you saw the demonstrative exhibits that is the evidence in this case.

You also may have noticed the exhibits have been numbered. The numbers assigned to the exhibits are for convenience and in order to ensure an orderly procedure. You should draw no inference from the fact that a particular exhibit was assigned a particular number, or that there may be gaps in the numbers sequence.

Authority:

Orexo AB v. Actavis Elizabeth, LLC, C.A. No. 1:17-cv-00205-CFC, D.I. 240, Proposed Joint Final Jury Instructions (D. Del. March 28, 2019) at 12; *Amgen v. Hospira*, C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. Sept. 22, 2017) at 8; *E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No. 1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 11; *EMC Corp. v. Pure Storage, Inc*., C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 11.

1.12 CONFIDENTIAL LABELS & REDACTIONS

The parties have entered into an agreement that would protect each respective party's confidential and sensitive business information from disclosure to the public or third parties. Under that agreement, the parties have added confidentiality labels to their documents, and have redacted, which means that they have obscured or removed information, from documents to protect the confidential nature of the information.

You may have seen documents with confidentiality labels or redactions during trial. The use of confidentiality labels and redactions has no bearing on the evidence, and should not be construed in any way against any party.

Authority:

F'Real Foods, LLC v. Hamilton Beach Brands, Inc., C.A. No. 1:16-cv-00041-CFC, D.I. 255, Proposed Final Jury Instructions (D. Del. Apr. 28, 2019) at 10-11.

1.13 USE OF NOTES

You may use notes taken during trial to assist your memory. However, you should use caution in consulting your notes. There is always a tendency to attach undue importance to matters that you have written down. Some testimony that is considered unimportant at the time presented, and thus not written down, takes on greater importance later on in the trial in light of all of the evidence presented.

Therefore, you are instructed that your notes are only a tool to aid your own individual memory, and you should not compare notes with other jurors in determining the content of any testimony or in evaluating the importance of any evidence. Your notes are not evidence and are by no means a complete outline of the proceedings or a list of the highlights of the trial. Above all, your memory should be the greatest asset when it comes time to deliberate and render a decision in this case.

Authority:

Amgen v. Hospira, C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. Sept. 22, 2017) at 9; *E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No. 1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 12; *AVM Tech., LLC v. Intel Corp.*, C.A. No. 15-33-RGA-MPT, D.I. 719, Final Jury Instructions (D. Del. May 8, 2017) at 5; *EMC Corp. v. Pure Storage*,

Inc., C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 12.

2. THE PARTIES AND THEIR CONTENTIONS

I will now review for you the parties to this action, and the positions that you will have to consider in reaching your verdict. I will then provide you with detailed instructions on what each side must prove to win on each of its contentions.

To refresh your recollection, the parties are Genentech, Inc., the Plaintiff, and Amgen Inc., the Defendant. Genentech is asserting four U.S. patents in this case: (1) U.S. Patent No. 6,627,196 ("the '196 Patent"); (2) U.S. Patent No. 7,371,379 ("the '379 Patent"); (3) U.S. Patent No. 10,160,811 ("the '811 Patent") and (4) U.S. Patent No. 8,574,869 ("the '869 Patent"). I will refer to the '196, '379, and '811 patents collectively as the "Dosing Patents." I will refer to the '869 Patent as the Kao Manufacturing Patent. I will refer to all four patents collectively as the Patents-in-Suit.

Amgen filed a Biologics License Application ("BLA") for a biosimilar of Herceptin, a drug used to treat cancer. Herceptin was first marketed by Genentech in 1998, and its active ingredient is trastuzumab. Amgen began selling its FDA-approved trastuzumab biosimilar product, called Kanjinti, in the U.S by July 18, 2019. ABP 980 is the active ingredient found in Kanjinti.

I will now overview the positions each side has taken. Genentech alleges that Amgen infringed, is currently infringing, and will continue to infringe:

1. claims 11 and 22 of the ’196 Dosing Patent;
2. claims 11 and 21 of the ’379 Dosing Patent;
3. claims 6 and 7 of the ’811 Dosing Patent; and
4. claims 5 and 8 of the Kao Manufacturing Patent.

I will refer to these claims collectively as the Asserted Patent Claims. Additionally, Genentech contends Amgen’s infringement of the Asserted Claims is willful. Genentech seeks damages adequate to compensate for Amgen’s infringement.

[**GENENTECH’S PROPOSAL:** Amgen denies that it infringes any of the Asserted Patent Claims. Amgen further asserts that each of the Asserted Patent Claims is invalid. Amgen also denies that it has willfully infringed the Asserted Claims.] [**AMGEN’S PROPOSAL:** Amgen denies Genentech’s infringement allegations as to all Asserted Patent Claims. Amgen further asserts that each of the Asserted Patent Claims is invalid because the inventions claimed were not new and were obvious at the time Genentech claims to have invented them. Amgen also contends that the Asserted Claims of the Dosing Patents are invalid for incorrect inventorship and/or derivation. Amgen also contends that the Asserted Claims of the ’196 Dosing Patent, the ’379 Dosing Patent, and the Kao Manufacturing Patent are invalid because the patents do not sufficiently describe and enable the claimed inventions and the Asserted Patent Claims themselves are

indefinite. Amgen further contends the '869 patent is unenforceable for inequitable conduct.]

You will be asked to determine the issues of infringement, invalidity, willful infringement, [**AMGEN'S PROPOSAL:** inequitable conduct,] and damages according to instructions I will give you in a moment.

Authority:

Orexo AB v. Actavis Elizabeth, LLC, C.A. No. 1:17-cv-00205-CFC, D.I. 240, Proposed Joint Final Jury Instructions (D. Del. March 28, 2019) at 12-13; *Amgen v. Hospira*, C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. Sept. 22, 2017) at 10; *E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No. 1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 1; *AVM Tech., LLC v. Intel Corp*., C.A. No. 15-33-RGA-MPT, D.I. 719, Final Jury Instructions (D. Del. May 8, 2017) at 1; *EMC Corp. v. Pure Storage, Inc*., C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 1; *Gilead Sciences, Inc. v. Abbvie Inc.*, C.A. No. 13-2034-GMS, D.I., 310-8, Parties Proposed Final Instructions (D. Del. Aug. 8, 2016) at 32-33.

3. BURDENS OF PROOF

In any legal action, facts must be proven by a required standard of evidence, known as the "burden of proof." For each issue in this case, either Genentech or Amgen bears the burden of proof, which means that it bears the burden of persuading you to find in its favor. In a patent case such as this, there are two different burdens of proof. The first is called "preponderance of the evidence." The second is called "clear and convincing evidence."

For any issue on which a party bears the burden of proof by a **preponderance of the evidence**, that party has carried its burden if you find that what the party claims is more likely true than not, when considered in light of all of the evidence. Put differently, if you were to put each party's evidence on the opposite sides of a scale, the evidence supporting the party with the burden of proof would have to make the scales tip [**GENENTECH'S PROPOSAL:** somewhat on the side] [**AMGEN'S PROPOSAL:** in favor] of that party.

Here, Genentech has the burden of proving by a preponderance of the evidence that Amgen's actions have infringed, are currently infringing, and/or will infringe, directly or indirectly, the Asserted Claims of the '196 Dosing Patent, the '379 Dosing Patent, the '811 Dosing Patent, or the Kao Manufacturing Patent. If you find that Amgen infringed a valid patent, then Genentech also has the burden of proving the amount of damages by a preponderance of the evidence. Genentech

also has the burden of proving by a preponderance of the evidence that Amgen's infringement was willful.

For any issue on which a party bears the burden of proof by **clear and convincing evidence**, that party has carried its burden if you find that the party with the burden has caused you to have an abiding conviction that the truth of that party's factual contention is highly probable, when considered in light of all of the evidence. Proof by clear and convincing evidence is a higher burden than proof by a preponderance of the evidence.

Here, Amgen has the burden of proving by clear and convincing evidence that the Asserted Patent Claims are invalid.

Authority:

Amgen v. Hospira, C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. Sept. 22, 2017) at 12; *E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No. 1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 3; *AVM Tech., LLC v. Intel Corp*., C.A. No. 15-33-RGA-MPT, D.I. 719, Final Jury Instructions (D. Del. May 8, 2017) at 3; *EMC Corp. v. Pure Storage, Inc*., C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 3; *Integra Lifesciences I, Ltd. v. Merck KGaA*, No. 3:96-CV-01307-B-AJB, D.I. 876, Proposed Jury Instructions (S.D. Cal. Mar. 16, 2000).

4. PATENT CLAIMS

4.1 THE ROLE OF CLAIMS IN THE PATENT

Before you can decide the issues in this case, you will need to understand the role of patent "claims." The patent claims are the numbered sentences at the end of each patent. The claims are important because the words of a claim define the scope of the patent right. The figures and text in the rest of the patent are intended to provide a description and/or examples of the claimed invention and provide a context for the claims, but the claims define the extent of the patent's coverage. Each claim may cover more or less than another claim. Therefore, what a patent covers depends, in turn, on what each of its claims covers.

Authority:

Orexo AB v. Actavis Elizabeth, LLC, C.A. No. 1:17-cv-00205-CFC, D.I. 240, Proposed Joint Final Jury Instructions (D. Del. March 28, 2019) at 15; *Amgen v. Hospira*, C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. Sept. 22, 2017) at 12*; E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No. 1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 14; *EMC Corp. v. Pure Storage, Inc*., C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 16.

4.2 INDEPENDENT AND DEPENDENT CLAIMS

Claims can be stated in two different ways in a patent. The first way a patent claim can be stated is in the form of an "independent" claim. An "independent" claim sets forth all of the requirements that must be met in order for a process, [**GENENTECH'S PROPOSAL:** a product made using a process,] or the use of a product according to a method to be covered by that claim, and thus infringe that claim. An independent claim is read alone to determine its scope. Claim 7 of the '811 Dosing Patent is an independent claim.

The second way a claim can be stated is in the form of a "dependent" claim. A dependent claim does not itself recite all of the requirements of the claim but instead incorporates the requirements of another claim or claims and adds its own additional requirements. In this way, the claim "depends" on another claim or claims. To determine what a dependent claim covers, it is necessary to look at both the dependent claim and any other claims from which it depends. For example, claim 6 of the '811 Dosing Patent is a dependent of claim 1 and, as a result, claim 6 includes all of the requirements of claim 1 plus the additional requirements of claim 6. Claims 11 and 22 of the '196 Dosing Patent are dependent claims. Claims 11 and 21 of the '379 Dosing patents are dependent as well. Finally, claims 5 and 8 of the Kao Manufacturing Patent are also dependent claims.

A process, [**GENENTECH'S PROPOSAL:** a product made using a process] or the use of a product according to a method is covered by, and therefore infringes, a dependent claim only if it meets all of the requirements of both the dependent claim and the claim or claims from which the dependent claim depends.

Authority:

Amgen v. Hospira, C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. Sept. 22, 2017) at 14; *E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No. 1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 15; *AVM Tech., LLC v. Intel Corp.*, C.A. No. 15-33-RGA-MPT, D.I. 719, Final Jury Instructions (D. Del. May 8, 2017) at 14; *EMC Corp. v. Pure Storage, Inc.*, C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 17.

4.3 CLAIM CONSTRUCTION[2]

The law says that it is the Court's duty to define the terms of patent claims. I have already defined the meaning of some of the words of the patent claims that you are considering in this case. These definitions have been provided to you, and they are attached to these jury instructions.

You must accept my definition of these words in the patent claims as correct. You must use the definitions I give you for each claim to make your decisions as to whether the claim is infringed or invalid. You must ignore any different definitions used by the witnesses or the attorneys. You should not take my definition of the language of the patent claims as an indication that I have a view regarding how you should decide the infringement or invalidity issues that you are being asked to decide. These issues are yours to decide. When I have not defined a term, you should give it its ordinary meaning.

Authority:

Amgen v. Hospira, C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. Sept. 22, 2017) at 14; *E.I. DuPont de Nemours & Co. v. Unifrax I LLC*,

[2] An instruction on claim construction is required only if the Court construes the term "following fermentation" in the Kao Manufacturing Patent and the Kao Manufacturing Patent remains in the case.

C.A. No. 1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 17; *EMC Corp. v. Pure Storage, Inc.*, C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 18.

5. INFRINGEMENT

5.1 INFRINGEMENT GENERALLY

Patent law provides that any person or business entity that imports, makes, uses, sells, or offers to sell without the patent owner's permission, any product or method covered by at least one claim of a United States patent before the patent expires, infringes the patent. Patent law also provides that importing, making, using, or selling within the United States a product made using a patented process before the patent expires is also patent infringement.

I will now instruct you how to decide whether Amgen has infringed or is currently infringing any of the Asserted Patent Claims. Infringement is assessed on a claim-by-claim basis. Therefore, there may be infringement as to one claim but no infringement as to another.

Genentech must prove that all the requirements of infringement are met by a preponderance of the evidence.

A claim may be infringed by: (1) direct infringement; and/or (2) indirect infringement. Genentech contends Amgen has and is directly infringing the Kao Manufacturing Patent. Genentech also alleges Amgen has and is inducing infringement of the '196, '379 and '811 Dosing Patents by encouraging others, including doctors, to directly infringe the methods recited in these patents.

[**GENENTECH'S PROPOSAL:** Genentech also alleges that Amgen's filing of its

BLA is an act of infringement of all the Asserted Patent Claims.] I will now explain each of these types of infringement in more detail.

Authority:

Orexo AB v. Actavis Elizabeth, LLC, C.A. No. 1:17-cv-00205-CFC, D.I. 240, Proposed Joint Final Jury Instructions (D. Del. March 28, 2019) at 18; *E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No. 1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 18; *EMC Corp. v. Pure Storage, Inc*., C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 19; Federal Circuit Bar Association Model Patent Jury Instructions § 3.1 (2016) at 18; *Sandoz Inc. v. Amgen Inc*., 137 S. Ct. 1664, 1670, 198 L. Ed. 2d 114 (2017).

5.2 DIRECT INFRINGEMENT

Direct infringement requires unauthorized practice of a patented method, or the unauthorized making, use, sale, offer for sale, or importation of a product made using a patented process during the time when the patent was in force. [**GENENTECH'S PROPOSAL:** Someone can directly infringe a patent without knowledge of the patent or without the knowledge that their actions are infringing the patent. They also may directly infringe a patent even though they believe in good faith that what they are doing does not infringe a patent or if they believe in good faith that the patent is invalid.]

When considering direct infringement, you must compare the accused method or process with each claim that Genentech asserts is infringed, using my instructions as to the meaning of the patent claims. A patent claim is directly infringed only if Amgen practices each and every requirement in that patent claim.

Genentech contends that Amgen has infringed and is infringing the Kao Manufacturing Patent by marketing, selling, importing and/or manufacturing Kanjinti in the United States. To prove infringement, Genentech must prove by a preponderance of the evidence, that is, that it is more likely than not, that Amgen's actions meet the requirements of claim 5 or 8 of the Kao Manufacturing Patent.

If the accused method of manufacture of Kanjinti performs each step of a claim of the Kao Manufacturing Patent, then Amgen infringes the claim. If the

accused method of manufacture of Kanjinti does not perform one or more steps of a claim of the Kao Manufacturing Patent, then Amgen does not infringe that claim.[**AMGEN'S PROPOSAL:** Amgen's knowledge of the Kao Manufacturing Patent and Amgen's intent are irrelevant to your determination of infringement of the Kao Manufacturing Patent.]

[**AMGEN'S PROPOSAL:** Genentech does not accuse Amgen of direct infringement of the Dosing Patents, but Genentech does accuse Amgen of induced infringement of the Dosing Patents. In order to prove that Amgen induced infringement of the Dosing Patents, Genentech must prove an act of direct infringement of the Dosing Patents by a third party. To prove direct infringement of the Dosing Patents by a third party, Genentech must prove by a preponderance of the evidence that a direct infringer has used Kanjinti in performing every step of an Asserted Claim of the Dosing Patents.]

Authority:

Amgen v. Hospira, C.A. No. 1:15-cv-839-RGA, D.I. 300, Proposed Jury Instructions (D. Del. Sept. 7, 2017) at 31-32; Federal Circuit Bar Association Model Patent Jury Instructions § 3.1a (2016) at 18; *Global-Tech Appliances, Inc.v. SEB S.A.*, 563 U.S. 754, 761 n.2 (2011); AIPLA Model Patent Jury Instructions §§ 3.1-3.2 (2018) at 10-11; *Mirror Worlds, LLC v. Apple Inc.* 692 F.3d 1351, 1358 (Fed. Cir. 2012).

5.3 INDUCED INFRINGEMENT

[**GENENTECH'S PROPOSAL:** Genentech alleges that Amgen infringes claim 11 or 22 of the '196 Dosing Patent, claim 11 or 21 of the '379 Dosing Patent, or claims 6 or 7 of the '811 Dosing Patent by inducing infringement. To find that Amgen induced infringement, it is not necessary to show that Amgen directly infringed the claims itself.

To prove inducement, Genentech must establish by a preponderance of the evidence, more likely than not, that:

1. A third party, such as a doctor or others working at the direction or under the control of a doctor, directly infringes that claim by performing each step of the claim;

2. Amgen took action intending to cause the infringing acts by the third party; and

3. Amgen was aware of the Dosing Patent and knew that the acts, if taken by the third party, would constitute infringement of the Dosing Patent claim.

In order to show a third party has directly infringed, Genentech must only prove that the third party performed all steps of the claimed method; it need not prove that all steps were performed with Kanjinti.

To find induced infringement, you must find that Amgen made statements or took actions directed to promoting or encouraging infringement, such as advertising an infringing use or instructing how to engage in an infringing use. A product label may demonstrate intent to cause infringing acts if it encourages, recommends, or promotes an infringing use.]

[**AMGEN'S PROPOSAL**: Genentech alleges that Amgen infringes claim 11 or 22 of the '196 Dosing Patent, claim 11 or 21 of the '379 Dosing Patent, or claims 6 or 7 of the '811 Dosing Patent by inducing infringement. To find that Amgen induced infringement, it is necessary to show that someone directly infringes the claim itself.

To prove inducement, Genentech must establish by a preponderance of the evidence that:

1. A third party, such as a doctor or others working at the direction or under the control of a doctor, directly infringes that claim by performing each and every step of the claim using Kanjinti;

2. Amgen took action intending to cause the infringing acts by the third party;

3. Amgen was aware of the Dosing Patent and knew that the acts, if taken by the third party, would constitute infringement of the Dosing Patent claim; and

4. Amgen's alleged inducement, as opposed to other factors, actually caused the third party to perform each and every step of an Asserted Claim of a Dosing Patent.

If you find that Amgen was aware of the Dosing Patents, but believed that the acts it encouraged did not infringe those patents, Amgen cannot be liable for inducement.

In order to establish active inducement of infringement, it is not sufficient that a third party itself directly infringes the claim. It is also not sufficient that Amgen knew of acts of direct infringement. Rather, in order to find induced infringement, you must find that Amgen specifically intended and caused the third party to carry out each and every requirement of an Asserted Claim of the Dosing Patents using Kanjinti.

To show induced infringement, it is not sufficient to show that the drug label permits an infringing use; permission is different from encouragement.]

Authority:

Orexo AB v. Actavis Elizabeth, LLC, C.A. No. 1:17-cv-00205-CFC, D.I. 240, Proposed Joint Final Jury Instructions (D. Del. March 28, 2019) at 21; Federal Circuit Bar Association Model Jury Instructions § 3.2; *Amgen v. Hospira*, C.A. No. 1:15-cv-839-RGA, D.I. 300, Proposed Jury Instructions (D. Del. Sept. 7, 2017) at

34-35; American Intellectual Property Law Association Model Patent Jury Instructions § 3.10 (2018) at 18-19; 35 U.S.C. § 271(b); *Global-Tech Appliances, Inc. v. SEB, S.A.*, 131 S. Ct. 2060 (2011); *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1021 (Fed. Cir. 2015) (en banc); *Takeda Pharms., USA v. West-Ward Pharm. Group*, 785 F.3d 625, 630-631 (Fed. Cir. 2015); *Info-Hold, Inc. v. Muzak LLC*, 783 F.3d 1365, 1372-1373 (Fed. Cir. 2015); *DSU Medical Corp. v. JMS Co.*, 471 F.3d 1293, 1304-05 (Fed. Cir. 2006) (en banc) (quoting *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005)); *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1365 (Fed. Cir. 2004); *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1342 (Fed. Cir. 2003); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990); *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1468-69 (Fed. Cir. 1990); *Mirror Worlds, LLC v. Apple Inc.* 692 F.3d 1351, 1358 (Fed. Cir. 2012); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1059-60 (Fed. Cir. 2010); *Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1341 (Fed. Cir. 2008); *Metro-Goldwyn-Mayer Studios*, 545 U.S. at 936; *Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015); *HZNP Medicines LLC v. Actavis Laboratories UT, Inc.*, --- F.3d ----, 2019 WL 5076226, at *16-17 (Fed. Cir. 2019); *Shire LLC v. Amneal Pharms., LLC*, C.A. No. 11-3781 (SRC), 2014

WL 2861430, at *5-6 (D.N.J. Jun. 23, 2014) (reversed on different grounds); *Shire, LLC v. Amneal Pharms., LLC.*, 802 F.3d 1301 (Fed. Cir. 2015)); *In re Depomed Patent Litig.*, C.A. No. 13-4507 (CCC-MF), 2016 WL 7163647, at *63, *69 (D.N.J. Sept. 30, 2016); *Dynacore Holdings v. U.S. Philips Corp.*, 363 F.3d 1263, 1274 (Fed. Cir. 2004; *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920 (2015); *DSU Med. Corp.*, 471 F. 3d at 1307; *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111 (2014).

5.4 [**GENENTECH'S PROPOSAL:** INFRINGEMENT BY FILING A BIOLOGICS LICENSE APPLICATION[3]

It is an act of infringement to submit a Biologics License Application ("BLA") seeking FDA approval to commercially manufacture, use, or sell a biosimilar product that is claimed in a patent or the use of which is claimed in a patent before the expiration of such a patent. The determination of whether the product or proposed use of the product directly infringes a claim or whether it demonstrates that the filer of the application would indirectly infringe the claim upon manufacture, use, or sale of the product is made based on the content of the BLA, including the instructions for use of the product (also called the "label" or "prescribing information") and the manufacturing process for the product that the applicant seeks approval to use. To show infringement by the submission of the BLA, Genentech must prove by a preponderance of the evidence that the prescribing information for which Amgen sought approval included instructions in its proposed label that will cause at least some users to infringe the asserted

[3] Amgen objects to including any instruction regarding infringement by filing a Biologics License Application, for the reasons Amgen will explain in its supplemental briefing on jury instructions.

method claims of a Dosing Patent or the manufacturing process for which Amgen sought approval infringes a claim of the Kao Manufacturing Patent.]

Authority:

35 U.S.C. § 271(e)(2)(C)(i); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997); *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357, 1369 (Fed. Cir. 2017); *Amgen Inc. v. Sandoz Inc.*, 923 F.3d 1023, 1030 (Fed. Cir.), *reh'g granted, opinion modified*, 776 F. App'x 707 (Fed. Cir. 2019).

5.5 [**AMGEN'S PROPOSAL:** DETERMINING WHETHER THIRD PARTIES HAD AN IMPLIED LICENSE TO PRACTICE THE DOSING PATENTS

One who owns a patent as patentee or assignee, having the right to exclude others from making, using, or selling what is claimed, may agree to let another do one or more of those acts. This is called a license, and the person allowed to do the set of acts is a licensee.

One type of license is an implied license. An implied license exists where (1) the patentee, through statements or conduct, gave an affirmative grant of consent or permission to make, use, or sell to the alleged infringers; (2) the alleged infringer relied on that statement or conduct; and (3) the alleged infringer would, therefore, be materially prejudiced if the patentee were allowed to proceed with a claim of infringement against the alleged infringer. The sale of a product without restriction grants an implied license to any patents owned by the seller of the product to which the parties might reasonably contemplate the product will be put.

If any third party, such as an oncologist, had an implied license from Genentech to practice any step of the Asserted Claims of the Dosing Patents,

Amgen cannot be liable for induced infringement based on that third party's use of the Dosing Patents under the implied license from Genentech.]

[GENENTECH'S PROPOSAL:[4]

One who owns a patent as patentee or assignee, having the right to exclude others from making, using, or selling what is claimed, may agree to let another do one or more of those acts. This is called a license, and the person allowed to do the set of acts is a licensee.

The burden of proving that an implied license exists is on Amgen, as the party asserting an implied license as a defense to infringement.

An implied license is a form of implied-in-fact contract. In order to prove the defense of implied license, Amgen must establish by a preponderance of the evidence that (1) there was an existing relationship between Genentech and each direct infringer (such as a doctor, or person acting at the direction or under the control of a doctor) (2) within that relationship, Genentech transferred a right to use Kanjinti according to the method covered by the Dosing Patents; (3)

[4] Genentech objects to inclusion of any instruction regarding implied license, for the reasons Genentech will explain in its supplemental briefing on jury instructions. Genentech offers this proposal only to the extent an instruction on implied license is included.

Genentech transferred the right in exchange for some value from the direct infringer.

Even where all the elements of implied license are met, they merely create a presumption of implied license which can be overcome by a clear indication of intent to the contrary.

You can only find an implied license if you find that Amgen has proven that a right to use Kanjinti according to the method covered by the Dosing Patents was granted to each direct infringer.]

Authority:

Augustine Med., Inc. v. Progressive Dynamics, Inc., 194 F.3d 1367, 1370 (Fed. Cir. 1999); *Wang Labs, Inc. v. Mitsubishi Electronic Am.*, 103 F.3d 1571, 1576, 1579 (Fed. Cir. 1997); *Winbond Electronics Corp. v. Int'l Trade Com'n*, 262 F.3d 1363, 1374 (Fed. Cir. 2001), *opinion corrected* 275 F.3d 1344 (Fed. Cir. 2001); *Hewlett-Packard Co. v. Repeat-O-Type Stencil Mfg. Corp.*, 123 F.3d 1445, 1451 (Fed. Cir. 1997); *Anton/Bauer, Inc. v. PAG, Ltd.* 329 F.3d 1343, 1350 (Fed. Cir. 2003); *Gen. Protecht Group, Inc. v. Leviton Mfg. Co., Inc*., 651 F.3d 1355, 1361 (Fed. Cir. 2011); *Sherwin-Williams Co. v. PPG Indus., Inc.*, No. 2:17-CV-01023-JFC, 2019 WL 7494994, at *10 (W.D. Pa. Nov. 11, 2019).

6. INVALIDITY[5] [6]

6.1 INVALIDITY GENERALLY

In this case, Amgen contends that the Asserted Patent Claims are invalid under a variety of legal concepts. I will explain these legal concepts in a moment. You must consider each of these patent claims separately and individually in making your determination. [**AMGEN PROPOSAL:** Amgen bears the burden of proving the invalidity of each Asserted Patent Claim by clear and convincing evidence.]

Authority:

Amgen v. Hospira, C.A. No. 1:15-cv-839-RGA, D.I. 300, Proposed Jury Instructions (D. Del. Sept. 7, 2017) at 41; American Intellectual Property Law

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[5] Genentech objects to including any instruction regarding derivation, incorrect inventorship, or inequitable conduct, for the reasons Genentech will explain in its supplemental briefing on jury instructions. Genentech reserves its right to consider additional jury instructions related to derivation, incorrect inventorship, and inequitable conduct pending the Court's decision on its motion to strike (D.I. 445).

[6] The parties reserve the right to propose revised jury instructions pending the outcome of the Court's decisions on indefiniteness and claim construction. Amgen's pending indefiniteness motion was last presented at the October 16, 2019 hearing and in supplemental briefing (D.I. 271, 448).

Association Model Patent Jury Instructions § 4 (2018) at 21; *EMC Corp., et al., v. Pure Storage, Inc.*, C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. Mar. 15, 2016); *Erfindergemeinschaft UroPep GbR v. Eli Lilly and Company*, No. 2:15-CV-1202, 2017 WL 959592 at *6 (E.D. Tex. Mar. 13, 2017) (Bryson, J., by designation); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1358 (Fed. Cir. 2004).

6.2 [**GENENTECH'S PROPOSAL:** PRESUMPTION OF VALIDITY[7]

Patents are issued by the Patent and Trademark office, often called the PTO. Issued patents are presumed to be valid. When a party challenges a patent's validity, the party bears the burden of demonstrating the PTO was wrong.

Because the law presumes issued patents are valid, Amgen bears the burden of proving the invalidity of each Asserted Claim by clear and convincing evidence.]

Authority:

CNH Am. LLC v. Kinze Mfg., C.A. No. 08-945-GMS, Final Jury Instructions, D.I. 301 (D. Del. Feb. 10, 2011) at 29.

[7] Amgen objects to including any instruction regarding a presumption of validity, for the reasons Amgen will explain in its supplemental briefing on jury instructions.

6.3 PERSON OF ORDINARY SKILL IN THE ART

Whether a claim in a patent is invalid is determined from the perspective of [**GENENTECH'S PROPOSAL:** the hypothetical] [**AMGEN'S PROPOSAL:** a] person of ordinary skill in the art as of the priority date. The person of ordinary skill is a hypothetical person who is presumed to be aware of all the pertinent prior art. The person of ordinary skill is also a person of ordinary creativity who can use common sense to [**GENENTECH'S PROPOSAL:** fit the teachings of prior art together] [**AMGEN'S PROPOSAL:** solve problems in this field]. In this case, Genentech asserts that the priority dates of the patents are: [8]

1. August 27, 1999 for the '196, '379, and '811 Dosing Patents.

2. July 9, 2007 for the Kao Manufacturing Patent.

In deciding what the level of ordinary skill is, you should consider all of the evidence introduced at trial, including but not limited to: (1) the levels of education and experience of the inventor and other persons actively working in the field; (2) the types of problems encountered in the field; (3) prior art solutions to those

[8] Amgen has asserted a derivation theory that is the subject of Genentech's pending motion to strike. (D.I. 445). Genentech reserves the right assert an earlier priority date if Amgen's derivation theory is allowed. Amgen reserves the right to object to any assertion of an earlier priority date.

problems; (4) rapidity with which innovations are made; and (5) the sophistication of the technology.

Authority:

35 U.S.C. § 103; *F'Real Foods, LLC v. Hamilton Beach Brands, Inc.*, C.A. No. 1:16-cv-00041-CFC, D.I. 255, Proposed Final Jury Instructions (D. Del. Apr. 28, 2019) at 22; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420-22 (2007); *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 666-67 (Fed. Cir. 2000); *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985); *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696-97 (Fed. Cir. 1983); *Innovention Toys, LLC v. MGA Entm't*, 637 F.3d 1314, 1323 (Fed. Cir. 2011); *EMC Corp. v. Pure Storage, Inc.*, C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 27.

6.4 THE WRITTEN DESCRIPTION REQUIREMENT

Patent law requires a patent's specification to contain a written description of the claimed invention. This is referred to as the written description requirement. You must determine whether the specification satisfies this requirement from the viewpoint of the person of ordinary skill in art as of the patent's priority date. The written description requirement is satisfied if the person of ordinary skill in the art would have recognized that it describes the full scope of the claimed invention as it is finally claimed in the issued patent. [**GENENTECH'S PROPOSAL:** A specification does not need to spell out every detail of the invention to satisfy the written description requirement and the exact words found in the claim do not need to be used. Nor are specific examples required. Only enough must be included in the specification to convey to the person of ordinary skill in the art that the inventor possessed the full scope of the invention.] [**AMGEN'S PROPOSAL:** A specification does not need to contain the exact words found in the claim to meet the written description requirement. Nor are specific examples required. The specification must convey to a person of ordinary skill in the art that the inventor actually possessed the full scope of the invention by the filing date of the claimed application.]

The issue of written description is decided on a claim-by-claim basis. Amgen contends the following claims are invalid for lack of a sufficient written

description: (1) claims 11 and 22 of the '196 Dosing Patent; (2) claims 11 and 21 of the '379 Dosing Patent; and (3) claims 5 and 8 of the Kao Manufacturing Patent.

[**GENENTECH'S PROPOSAL:** Amgen must prove by clear and convincing evidence that the specifications fail to meet the law's requirements for written description of an invention.]

Authority:

Monsanto Co. v. Syngenta Seeds, Inc., C.A. No. 04-305-SLR, D.I. 364, Joint Proposed Final Jury Instructions (D. Del. May 8, 2006) at 63; *Gilead Sciences, Inc. v. AbbVie Inc.*, C.A. No. 13-2034-GMS, D.I., 310-8, Parties Proposed Final Instructions (D. Del. Aug. 8, 2016) at 76; Federal Circuit Bar Association Model Patent Jury Instructions § 4.2a (2016) at 40; AIPLA Model Patent Jury Instructions § 9 (2015); *see also* 35 U.S.C. §§ 112, 120; *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991); *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010); *Bristol-Myers Squibb Co. v. Merck & Co. Inc.*, C.A. No. 14-1131-GMS, D.I. 262, [Proposed] Final Jury Instructions (D. Del. Jan. 24, 2017) at 55-56.

6.5 THE ENABLEMENT REQUIREMENT

Patent law also requires a patent's written description to be "enabled." This means that the written description of a patent must be sufficiently detailed to allow those skilled in the art to make and use the full scope of the claimed invention.

To meet this requirement, the patent disclosure must allow the person of ordinary skill in the art to practice the claimed invention without undue experimentation. Because descriptions in patents are addressed to persons of ordinary skill in the art, an applicant for a patent need not expressly include information that is commonly understood by persons of ordinary skill in the art. Moreover, the fact that some experimentation may be required for a skilled person to practice the claimed invention does not mean that the specification is not enabling. A specification is enabling so long as undue experimentation is not needed.

Factors to consider in determining whether a disclosure would require undue experimentation include testimony (including but not limited to expert opinion) and other evidence indicating:

1. The time and cost of any necessary experimentation;
2. how routine and necessary experimentation would be to persons of ordinary skill in the art;

3. whether the patent discloses specific working examples of the claimed invention;
4. whether the inventor attempted but failed to enable his invention in a commercial product embodying the claimed invention;
5. the amount of guidance presented in the patent;
6. the nature and predictability of the technical field of the claimed invention;
7. the level of ordinary skill in the art; and
8. the scope of the claimed invention.

None of these factors alone is dispositive. Rather, you must make your decision whether or not the degree of experimentation required for the person of ordinary skill in the art to make and use the full scope of the claimed invention is undue based upon all of the evidence presented to you. You should weigh these factors and determine whether or not, in the context of the claimed invention and the state of the art as of the patent's priority date, the person of ordinary skill in the art would need to experiment unduly to make and use the full scope of the claimed invention.

The issue of enablement is decided on a claim-by-claim basis. Amgen contends the following claims are invalid for lack of enablement: (1) claims 11 and 22 of the '196 Dosing Patent; (2) claims 11 and 21 of the '379 Dosing Patent; and (3) claims 5 and 8 of the Kao Manufacturing Patent.

[**GENENTECH'S PROPOSAL:** Amgen has the burden of proving lack of enablement of a claim by clear and convincing evidence.**]**

Authority:

CNH Am. LLC v. Kinze Mfg., C.A. No. 08-945-GMS, Final Jury Instructions, D.I. 301 (D. Del. Feb. 10, 2011) at 47-48.

6.6 INDEFINITENESS[9]

Patent law requires that patent claims be written in certain ways. Claims must be sufficiently clear that a person of ordinary skill art reading them is able to determine with reasonable certainty what the claims cover and do not cover.

The amount of detail required for a claim to be definite depends on the particular invention, the prior art, and the description of the claimed invention contained in the patent. A patent claim, when read along with the rest of the patent, must reasonably inform a person of ordinary skill in the art what the patent claim covers. Simply because some claim language may not be precise does not automatically render a claim invalid. If the claim's language is imprecise, then you must determine whether a person of ordinary skill in the art would understand what is covered when the claim is read in light of the disclosure of the patent.

The issue of indefiniteness is decided on a claim-by-claim basis. Amgen contends that claims 11 and 22 of the '196 Dosing Patent and claims 11 and 21 of the '379 Dosing Patent are indefinite.

[**GENENTECH'S PROPOSAL:** It is Amgen's burden to prove by clear and convincing evidence that a person of ordinary skill in the art would not

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[9] An instruction regarding indefiniteness for the Kao Manufacturing Patent is required only if the Kao Manufacturing Patent remains in the case and the Court has not resolved the issue of indefiniteness by the time of trial.

understand with reasonable certainty what is, and what is not, covered by the claims.]

Authority:

CNH Am. LLC v. Kinze Mfg., C.A. No. 08-945-GMS, Final Jury Instructions, D.I. 301 (D. Del. Feb. 10, 2011) at 46.

6.7 PRIOR ART AND PRIOR PUBLIC USE

Under the patent laws, a patent is invalid if the invention claimed in the patent was not new or was obvious in light of what came before. That which came before is referred to as the "prior art." Prior art can take the form of documents or things [**AMGEN'S PROPOSAL:** public knowledge, or public use.]

Prior art includes any of the following received into evidence during trial:

- [**AMGEN'S PROPOSAL:** Any product or method that was publicly known or used by others in the United States before the claimed invention was invented;]
- Any product or method that was patented or described in a printed publication in the United States or a foreign country before the claimed invention was invented;
- Patents that issued more than one year before the filing date of the patent, or before the priority date for the patent;
- Publications having a date more than one year before the filing date of the patent, or before the priority date for the patent;
- [**AMGEN'S PROPOSAL:** Any product or method that was in public use or on sale in the United States before the filing date of the patent, or before the priority date for the patent;]

- [**AMGEN'S PROPOSAL:** Any method that was used by anyone before the named inventors' invention of the claimed method and that was not abandoned, suppressed, or concealed.]

In this case, you are to apply the following dates in determining the prior art date:[10]

1. August 27, 1999 for the '196, '379, and '811 Dosing Patents.
2. July 9, 2007 for the Kao Manufacturing Patent.

[**AMGEN'S PROPOSAL:** Genentech does not assert an invention date prior to these priority dates.]

In this case, Amgen contends that the following documents are prior art to either the '196, '379, and '811 Dosing Patents or the Kao Manufacturing Patent: [List to be provided based on evidence admitted during trial.]

[**GENENTECH'S PROPOSAL:** Amgen's burden of proof to show that the prior art renders a claim invalid never changes regardless of whether the U.S. Patent and Trademark Office considered the prior art. However, if the Patent Office considered a reference, it may be more difficult for Amgen to meet its

[10] Amgen has asserted a derivation theory that is the subject of Genentech's pending motion to strike. (D.I. 445). Genentech reserves the right assert an earlier priority date if Amgen's derivation theory is allowed. Amgen reserves the right to object to any assertion of an earlier priority date.

burden of proof to prove invalidity based on that reference.] [**AMGEN'S PROPOSAL:** The standard for assessing whether the prior art renders a claim invalid never changes regardless of whether the U.S. Patent and Trademark Office considered the prior art.]

Authority:

35 U.S.C. § 102 (Pre-AIA); *F'Real Foods, LLC v. Hamilton Beach Brands, Inc.*, C.A. No. 1:16-cv-00041-CFC, D.I. 255, Proposed Final Jury Instructions (D. Del. Apr. 28, 2019) at 33-35; *Amgen v. Hospira*, C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. September 22, 2017) at 22; AIPLA's Model Patent Jury Instructions, No. 5.0.1; Final Jury Instruction No. 5.1, *EMC Corp., et al., v. Pure Storage, Inc.*, No. 1:13-CV-01985-RGA (D. Del. Mar. 15, 2016); *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 110-111 (2011); *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1260 (Fed. Cir. 2012); *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1355-56 (Fed. Cir. 2000); *Grp. One, Ltd. v. Hallmark Cards, Inc.*, 407 F.3d 1297, 1306 (Fed. Cir. 2005); *EMC Corp. v. Pure Storage, Inc.*, C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 23; ABA Model Patent Jury Instructions, §§ 10.6.3 and 10.6.4; *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998); *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1570 (Fed. Cir. 1997).

6.8 ANTICIPATION

As I have explained, under the patent laws a patent is invalid if the invention claimed in the patent is not new in light of what came before. A person cannot obtain a valid patent on an invention if someone else has already made the same invention. In general, inventions are new when they have not been made, used, or disclosed before. The legal name for this type of challenge to the validity of a patent claim is "anticipation." In this case, Amgen contends the following patent claims are anticipated: (1) claims 11 and 22 of the '196 Dosing Patent; (2) claims 11 and 21 of the '379 Dosing Patent; (3) claims 6 and 7 of the '811 Dosing Patent; and (4) claims 5 and 8 of the Kao Manufacturing Patent.

Invalidity by anticipation requires that a single prior art reference disclosed each and every requirement, or limitation, of a claimed invention arranged as in the patent claim. You may not combine two or more items of prior art from the list of references presented to you to find anticipation unless I specifically instruct you that one reference incorporates another and the combination is treated as a single disclosure under the law. [**AMGEN'S PROPOSAL:** In particular, Hellmann, *Treatment with Anti-ErbB2 Antibodies*, United States Patent No. 8,309,087, issued November 13, 2012, filed May 9, 2011, claiming priority to application No. 09/209,023, filed December 10, 1998, incorporates by reference

Perry (Ed.), *The Chemotherapy Source Book* (1992), and the combination of the two is treated as a single disclosure under the law.] In determining whether every one of the elements of the claimed invention is found in a particular prior art reference, you should take into account what the person of ordinary skill in the art would have understood from his or her review of that reference.

Amgen also alleges claims 5 and 8 of the Kao Manufacturing Patent are inherently anticipated. A party asserting inherent anticipation must prove by clear and convincing evidence that the allegedly inherent element was necessarily present in that reference. The fact that it was likely is not sufficient. It is not required, however, that the person of ordinary skill in the art actually recognized or appreciated the inherent disclosure at the time the prior art reference was first known or used. Thus, the prior use of the patented invention that was unrecognized and unappreciated can still be an invalidating anticipating reference, provided the allegedly inherent feature was necessarily and inevitably present in the reference.

In determining whether a single prior art reference anticipates a patent claim, you should take into consideration not only what is expressly disclosed in that prior art reference but also what is inherently present or disclosed in that reference, or inherently results from its practice. A prior art reference inherently anticipates a patent claim if the element or feature missing from the reference

would necessarily result from what that reference teaches to the person of ordinary skill in the art.

Anticipation, including inherent anticipation, must be determined on a claim-by-claim basis. Where Amgen argues that a claim was anticipated, it must prove by clear and convincing evidence that such Asserted Patent Claim was not new based on the asserted prior art.

Authority:

Amgen v. Hospira, C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. Sept. 22, 2017) at 23-24*; E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No. 1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 25-26; *Net MoneyIN, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1369-70 (Fed. Cir. 2008); *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320-21 (Fed. Cir. 2004); *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377-78 (Fed. Cir. 2003); *Eibel Process Co. v. Minn. & Ontario Paper Co.*, 261 U.S. 45, 66 (1923); *Tilghman v. Proctor*, 102 U.S. 707, 711 (1880); *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999); *Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1342, 1347-48 (Fed. Cir. 1999); *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1554 (Fed. Cir. 1995); *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed. Cir. 1992); *Cont'l Can Co. USA v.*

Monsanto Co., 948 F.2d 1264, 1267-69 (Fed. Cir. 1991); *Buildex, Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1463 (Fed. Cir. 1988); *Advanced Display Systems, Inc. v. Kent State Univ.*, 212 F.3d 1271, 1283 (Fed. Cir. 2000).

6.9 OBVIOUSNESS

Even though a claimed invention may not have been identically disclosed or described before it was made by an inventor, in order to be valid, the claimed invention must also not have been obvious to the person of ordinary skill in the art of the claimed invention as of the patent's priority date. In this case, Amgen contends that all of the Asserted Patent Claims are obvious over certain references.

Amgen must prove by clear and convincing evidence that the claimed inventions of the Asserted Patent Claims would have been obvious to the person of ordinary skill in the art as of the patent's priority date. The issue is not whether the claimed inventions would have been obvious to you as a layman, to me as the judge, to the inventor, or to a genius in the field of technology, but whether it would have been obvious to the hypothetical person of ordinary skill in the art as of the patent's priority date.

Keep in mind that the existence of each and every element of the claimed invention in the prior art does not necessarily prove obviousness. Most inventions rely on building blocks of prior art.

In determining whether a claimed invention would have been obvious, you must consider: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art; and (3) the differences between the claimed invention and the prior art.

To determine the scope and content of the prior art, you must determine what prior art is reasonably pertinent to the particular problems the inventors faced. The person of ordinary skill in the art is presumed to be aware of all of the pertinent prior art.

I have already instructed you on how you are to determine the level of ordinary skill in the art. Once you have made that determination, you are to apply it in your determination of whether the claim would have been obvious.

The next factor that you must consider is the differences, if any, between the prior art and the claimed inventions.

[**GENENTECH'S PROPOSAL:** A claim is not proved obvious merely by demonstrating that each of the elements was independently known in the prior art.] Thus, in considering whether a claimed invention is obvious, you should consider whether at the time of the claimed invention there was a reason that would have prompted the person of ordinary skill in the art to combine the known elements in a way the claimed invention does. You may take into account such factors as: (1) whether the claimed invention was merely the predictable result of using prior art elements according to their known function(s); (2) whether the claimed invention provides an obvious solution to a known problem in the relevant field; (3) whether the prior art teaches or suggests the desirability of combining elements in the claimed invention; (4) whether the prior art teaches

away from combining elements in the claimed invention; (5) whether it would have been obvious to try the combinations of elements, such as when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions; and (6) whether the change resulted more from design incentives or other market forces.

To find that the prior art rendered the claimed invention obvious, you must find that it provided a reasonable expectation of success. [**AMGEN'S PROPOSAL**: Obviousness does not require absolute predictability, although at least some degree of predictability is required. There is no law-required minimum showing for a "reasonable expectation of success."]

In determining whether the claimed invention was obvious, consider each claim separately. Also, in determining whether a claimed invention would have been obvious, you must avoid using hindsight; that is, you should not consider what is known today or what was learned from the teachings of the Patents-in-Suit. You should not use the patent as a road map for selecting and combining items of prior art. You must put yourself in the place of [**GENENTECH'S PROPOSAL:** the hypothetical] [**AMGEN'S PROPOSAL:** a] person of ordinary skill in the art as of the patent's priority date. In arriving at your decision on the issue of whether the claimed inventions of the Patents-in-Suit would have been obvious to the person of ordinary skill in the art, you should take into account any "secondary

considerations," also called "objective indicia," that may shed light on the nonobviousness of the claimed invention. Genentech bears the burden of introducing any evidence of secondary considerations of nonobviousness. These secondary considerations include: (1) commercial success; (2) unexpected results; (3) skepticism by experts; (4) industry praise;[11] and (5) the copying of the invention by competitors.

[**GENENTECH'S PROPOSAL:** These objective indicia should be considered along with all the other evidence in the case in determining whether the claimed invention would have been obvious. However, there must be a connection between the secondary consideration and the claimed invention if this evidence is to be given weight by you in arriving at your conclusion on the obviousness issue.] [**AMGEN'S PROPOSAL:** These objective indicia are relevant to obviousness only if there is a connection, or nexus, between them and the invention covered by the patent claims. For example, commercial success is relevant to obviousness only if the success of the product is related to a feature of the patent claims. If the commercial success is the result of something else, such as innovative marketing, and not to a patented feature, then you should not consider it to be an indication of

[11] Industry praise is relevant as a secondary consideration only if the Kao Manufacturing Patent remains in the case.

non-obviousness. Likewise, if the commercial success is a result of another patent that prevented others from trying or implementing an obvious idea, then you should not consider commercial success to be an indication of non-obviousness.]

Authority:

F'Real Foods, LLC v. Hamilton Beach Brands, Inc., C.A. No. 1:16-cv-00041-CFC, D.I. 255, Proposed Final Jury Instructions (D. Del. Apr. 28, 2019) at 35-39; *Amgen v. Hospira*, C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. Sept. 22, 2017) at 25-27*; Amgen v. Hospira*, C.A. No. 1:15-cv-839-RGA, D.I. 300, Proposed Jury Instructions (D. Del. Sept. 7, 2017) at 50; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 405, 421 (2007); *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 662-63 (Fed. Cir. 2000); *Kinetic Concepts, Inc. v. Smith & Nephew Inc.*, 688 F.3d 1342, 1367 (Fed. Cir. 2012); *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1053 (Fed. Cir. 2016); *Neptune Generics, LLC v. Eli Lilly & Co.*, 921 F.3d 1372, 1378 (Fed. Cir. 2019); *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005); *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 740 (Fed. Cir. 2013); *E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No. 14-1250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 27-29; Federal Circuit Bar Association Model Patent Jury Instructions § 4.3c; Manual of Patent Examining

Procedure at 2143.02; *Acorda Therapeutics, Inc. v. Roxane Laboratories, Inc*., 903 F.3d 1310, 1333 (Fed. Cir. 2018).

6.10 DERIVATION[12]

The patent laws require that the inventor(s) on a patent be the first and true inventor(s) of the invention covered by the patent claims. An inventor on a patent is not the first and true inventor if he or she "derived" the claimed invention from someone else. An invention is said to be "derived" from another person if that other person conceived of the patented invention as a whole prior to the inventors named on the patent and communicated that conception to an inventor named in the patent. Conception of an invention occurs when a person has formed the idea of how to make and use every aspect of the patented invention, and all that is required is that it be made or used without the need for further inventive effort. [**GENENTECH'S PROPOSAL:** Conception requires more than a general goal or research plan; rather, it requires a definite and permanent, specific, settled idea encompassing all limitations of the claims. Communication of the conception to an inventor named in the patent must be sufficient to enable the person of ordinary skill in the art to implement the invention.]

[12] Genentech objects to the inclusion of an instruction regarding derivation, for the reasons Genentech will explain in its supplemental briefing on jury instructions. Genentech's proposal regarding this instruction is offered only to the extent an instruction on derivation is included.

[**AMGEN'S PROPOSAL:** For derivation, there is no requirement that the "communication" of the conception to the named inventor occur in the United States. Derivation may be of the claimed invention itself or of an obvious variation of the invention. If an inventor named on a patent derived the patented invention from someone else, then the patent claims covering the invention are invalid.]

Amgen contends that, [**AMGEN'S PROPOSAL:** to the extent the Asserted Claims of the Dosing Patents recite any invention at all,] the Dosing Patents are invalid because the claimed invention of the Asserted Claims of the Dosing Patents was derived from Dr. Brian Leyland-Jones.

[GENENTECH PROPOSAL: The listing of inventors on a patent is presumed to be correct.]

[**AMGEN'S PROPOSAL**: Amgen contends that no later than March 1999, Dr. Leyland-Jones conceived of the idea to prescribe Herceptin at an initial dose of 8 mg/kg and a plurality of subsequent doses at 6 mg/kg, each dose given every three weeks, as claimed in the Dosing Patents. Amgen also contends that Dr. Leyland-Jones communicated his conception of the dosing regimens recited in the Asserted Claims of the Dosing Patents to named inventor Dr. Sharon Baughman.][13]

[13] Amgen will explain the significance of its use of grey shading in its supplemental briefing on jury instructions.

Amgen must prove derivation by clear and convincing evidence.

[**AMGEN'S PROPOSAL**: If you find that Amgen has proved by clear and convincing evidence that the named inventors on the Dosing Patents derived the invention covered by the Asserted Claims of the Dosing Patents from Dr. Leyland-Jones, then you must find that the Asserted Claims of the Dosing Patents are invalid.]

Authority:

ABA Model Patent Jury Instructions, § 10.7; *Pannu* v. *Iolab Corp.*, 155 F.3d 1344, 1349 (Fed. Cir. 1998); *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1576-78 (Fed. Cir. 1997); *Oddzon Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1401 (Fed. Cir. 1997); *Lamb-Weston, Inc.* v. *McCain Foods, Ltd.*, 78 F.3d 540, 544 (Fed. Cir. 1996); *Price v. Symsek*, 988 F.2d 1187, 1190 (Fed. Cir. 1993); *Auxilium Pharms., Inc. v. Watson Labs., Inc.*, C.A. No. 12-3084 (JLL), 2014 WL 9859224 (D.N.J. Dec. 16, 2014); *Ex parte Andresen*, 212 USPQ 100, 102 (Bd. App. 1981); Manual of Patent Examining Procedure at § 2137 (discussing 35 U.S.C. § 102(f)); 35 U.S.C. § 256; *Shum v. Intel Corp.*, 633 F.3d 1067, 1083 (Fed. Cir. 2010) (quoting *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1358 (Fed. Cir. 2004)); *Cumberland Pharm. Inc. v. Mylan Institutional LLC*, 846 F.3d 1213, 1218 (Fed. Cir. 2017); *Erfindergemeinschaft UroPep GbR v. Eli Lilly and*

Company, No. 2:15-CV-1202, 2017 WL 959592 at *6 (E.D. Tex. Mar. 13, 2017) (Bryson, J., by designation); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1358 (Fed. Cir. 2004).

6.11 INCORRECT INVENTORSHIP[14]

[**GENENTECH'S PROPOSAL:** The patent laws also require that the patent correctly name each and every inventor who contributed to the claimed invention. To prove incorrect inventorship, Amgen must prove by clear and convincing evidence that the alleged co-inventor(s) conceived of one or more limitations that is not insignificant in quality as compared to the full invention. It is not enough if the alleged co-inventor merely explained to the named inventors well-known concepts and/or the current state of the art.]

[**AMGEN'S PROPOSAL:** The patent laws also require that the patent correctly name each and every inventor who contributed to any of the claimed invention. For incorrect inventorship, unlike derivation, the alleged co-inventor(s) need not have conceived of the claimed invention as a whole, but rather need only have conceived of a single limitation of the claimed invention. A patent is invalid if it fails to correctly name each and every inventor who contributed to any limitation of the claimed invention.]

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[14] Genentech objects to the inclusion of an instruction regarding incorrect inventorship, for the reasons Genentech will explain in its supplemental briefing on jury instructions. Genentech's proposal regarding this instruction is offered only to the extent an instruction on incorrect inventorship is included.

Amgen contends that, [**AMGEN'S PROPOSAL:** to the extent the Asserted Claims of the Dosing Patents recite any invention at all,] the Dosing Patents fail to name Dr. Brian Leyland-Jones as an inventor.

[**GENENTECH'S PROPOSAL:** The listing of inventors on a patent is presumed to be correct.]

[**AMGEN'S PROPOSAL**: Specifically, Amgen contends that no later than March 1999, Dr. Leyland-Jones conceived of the idea to prescribe Herceptin at an initial dose of 8 mg/kg and a plurality of subsequent doses at 6 mg/kg, each dose given every three weeks, as claimed in the Dosing Patents.][15]

Amgen must prove incorrect inventorship by clear and convincing evidence.

[**AMGEN'S PROPOSAL**: If you find that Amgen has proved by clear and convincing evidence that someone other than Dr. Baughman or Dr. Shak contributed to any limitation recited in the Asserted Claims of the Dosing Patents, then you must find that the Asserted Claims of the Dosing Patents are invalid.]

Authority:

Pannu v. *Iolab Corp.*, 155 F.3d 1344, 1349 (Fed. Cir. 1998); *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1576-78 (Fed. Cir. 1997); *Oddzon*

[15] Amgen will explain the significance of its use of grey shading in its supplemental briefing on jury instructions.

Prods., Inc. v. Just Toys, Inc., 122 F.3d 1396, 1401 (Fed. Cir. 1997); *Lamb-Weston, Inc.* v. *McCain Foods, Ltd.*, 78 F.3d 540, 544 (Fed. Cir. 1996); *Price* v. *Symsek*, 988 F.2d 1187, 1190 (Fed. Cir. 1993); *Auxilium Pharms., Inc. v. Watson Labs., Inc.*, C.A. No. 12-3084 (JLL), 2014 WL 9859224 (D.N.J. Dec. 16, 2014) (finding patent invalid due to derivation and/or improper inventorship); *Ex parte Andresen*, 212 USPQ 100, 102 (Bd. App. 1981); Manual of Patent Examining Procedure at § 2137. *Checkpoint Sys., Inc. v. All-Tag Sec. S.A.*, 412 F.3d 1331, 1337–38 (Fed. Cir. 2005); 35 U.S.C. § 256; *CardiAQ Valve Techs., Inc. v. Neovasc Inc.*, 708 F. App'x 654, 658 (Fed. Cir. 2017); *Acromed Corp. v. Sofamor Danek Grp., Inc.*, 253 F.3d 1371, 1379 (Fed. Cir. 2001); *Shum v. Intel Corp.*, 633 F.3d 1067, 1083 (Fed. Cir. 2010) (quoting *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1358 (Fed. Cir. 2004));*Cumberland Pharm. Inc. v. Mylan Institutional LLC*, 846 F.3d 1213, 1218 (Fed. Cir. 2017); *Erfindergemeinschaft UroPep GbR v. Eli Lilly and Company*, No. 2:15-CV-1202, 2017 WL 959592 at *6 (E.D. Tex. Mar. 13, 2017) (Bryson, J., by designation); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1358 (Fed. Cir. 2004).

6.12 [**AMGEN'S PROPOSAL:** INEQUITABLE CONDUCT[16]

Amgen contends that Genentech may not enforce the Kao Manufacturing Patent against Amgen because Genentech engaged in inequitable conduct before the Patent and Trademark Office when it obtained the Kao Manufacturing Patent. To prove that inequitable conduct occurred, Amgen must prove by clear and convincing evidence that the patent applicant or the applicant's attorney or representative withheld or misrepresented material information, and did so with an intent to mislead or deceive the Patent and Trademark Office.

Authority:

ABA Model Patent Jury Instructions, § 3.2.5.]

[16] Genentech objects to the inclusion of an instruction regarding inequitable conduct, for the reasons Genentech will explain in its supplemental briefing on jury instructions. Genentech's proposal regarding this instruction is offered only to the extent an instruction on inequitable conduct is included. Amgen proposes an instruction on inequitable conduct only if the Kao Manufacturing Patent remains in the case following the court's ruling on the issues of indefiniteness/claim construction.

7. DAMAGES

7.1 DAMAGES – GENERALLY

If you find that Amgen infringes any of the Asserted Patent Claims, and that those claims are not invalid [**AMGEN'S PROPOSAL:** or unenforceable], you must determine the amount of damages to be awarded Genentech for Amgen's infringement. On the other hand, if you find that each of the Asserted Patent Claims is either invalid, not infringed, [**AMGEN'S PROPOSAL:** or unenforceable**]**, then you should not consider damages in your deliberations.

Genentech must prove each element of its damages—including the amount of the damages—by a preponderance of the evidence, which means more likely than not.

If proven by Genentech, damages must be in an amount adequate to compensate Genentech for the infringement. The purpose of a damage award is to put Genentech in about the same financial position it would have been in if the infringement had not happened. But the damage award cannot be less than a reasonable royalty. You may not add anything to the amount of damages to punish an accused infringer or to set an example. You also may not add anything to the amount of damages for interest.

The fact that I am instructing you on damages does not mean that the Court believes that one party or the other should win in this case. My instructions about

damages are for your guidance only in the event you find in favor of Genentech. You will need to address damages only if you find that one or more of the Asserted Patent Claims are infringed, not invalid [**AMGEN'S PROPOSAL:** and not unenforceable].

Authority:

AIPLA Model Patent Jury Instruction 10.0; *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1241 (Fed. Cir. 2017); *Paper Converting Mach. Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 23 (Fed. Cir. 1984); *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 864 (Fed. Cir. 1985); *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1578 (Fed. Cir. 1989*); Micro Chem., Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1122 (Fed. Cir. 2003); *Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1238 (Fed. Cir. 2011); *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 868 (Fed. Cir. 2010); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1325 (Fed. Cir. 2009); 35 U.S.C. § 284 (2004); *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 507 (1964); *Dow Chem. Co. v. Mee Indus., Inc.*, 341 F.3d 1370, 1381-82 (Fed. Cir. 2003); *Vulcan Eng'g Co. v. FATA Aluminum, Inc.*, 278 F.3d 1366, 1376 (Fed. Cir. 2002); *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999); *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1108-09 (Fed. Cir. 1996); *Hebert v. Lisle Corp.*, 99 F.3d 1109,

1119 (Fed. Cir. 1996); *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1544-45 (Fed. Cir. 1995); *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 870 (Fed. Cir. 1993); *Fromson v. W. Litho Plate & Supply Co.*, 853 F.2d 1568, 1574 (Fed. Cir. 1988), *overruled on other grounds by Knorr-Bremse Systeme Fuer Nutzfahrzeuge v. Dana Corp.*, 383 F.3d 1337, 1342 (Fed. Cir 2004); *Del Mar Avionics, Inc. v. Quinton Instrument Co.*, 836 F.2d 1320, 1326 (Fed. Cir. 1987).

7.2 DAMAGES – KINDS OF DAMAGES THAT MAY BE RECOVERED

There are several kinds of damages that are available for patent infringement.

One kind of damages is lost profits, that is, the additional profits that the patentee would have made if the defendant had not infringed. You may hear this referred to as the "but for" test—which means, "what profits would the patent owner have made 'but for' the alleged infringement?" Lost profits can include not only the profits the patentee would have made on sales lost due to the infringement, but also, under certain circumstances, profits that the patentee lost from being unable to sell related products with those lost sales or from being forced to reduce its price for its product or other related products to compete.

[**AMGEN'S PROPOSAL:** Lost profits are limited to that portion of Herceptin's profits that are reasonably allocated to the infringed method patents, not to the entire profits of Genentech's Herceptin. The entire profits of Herceptin consist of the combined value of non-patented features of Herceptin, such as the antibody itself and its therapeutic effect, which are no longer patented, and the allegedly infringed patented method of dosing at 8 mg/kg initially followed by 6 mg/kg every three weeks, and the method for preventing disulfide bond reduction during the manufacturing process. If you award lost profits, the lost profits damages must be limited to that portion of Genentech's lost profits actually

attributable to Amgen's direct or induced infringement of Genentech's patented methods. Additionally, if you award lost profits, the lost profits damages must be limited only to lost profits that Genentech proved are caused by Amgen's infringement of Genentech's patented methods, rather than sales of Kanjinti that were put to non-infringing uses, or lost profits due to the activities of third parties, such as Genentech's licensees, who began selling trastuzumab biosimilar products on December 1, 2019.]

Another kind of patent damages is a reasonable royalty. A reasonable royalty is the amount that someone wanting to use the patented [**GENENTECH'S PROPOSAL**: invention][**AMGEN'S PROPOSAL:** process or method] would have agreed to pay to the patent owner and the patent owner would have accepted. A reasonable royalty is the minimum amount of damages that a patent owner can receive.

In awarding damages, you may award lost profits for some infringement and a reasonable royalty for other infringement. Alternatively, you may award only a reasonable royalty. [**AMGEN'S PROPOSAL:** In deciding whether to award damages, and what type of damages to award, you must separately consider the appropriate damage awards for infringement occurring before other competing trastuzumab biosimilars were available on the market (before December 1, 2019)

and infringement occurring after other competing trastuzumab biosimilars were available on the market (after December 1, 2019).]

Authority:

AIPLA Model Jury Instruction 10.2; 35 U.S.C. § 284; *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1241 (Fed. Cir. 2017); *Paper Converting Mach. Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 23 (Fed. Cir. 1984); *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 864 (Fed. Cir. 1985); *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1578 (Fed. Cir. 1989); *Micro Chem., Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1122 (Fed. Cir. 2003); *Rude v. Westcott*, 130 U.S. 152, 165 (1889); *Seymour v. McCormick*, 57 U.S. 480, 490-91 (1854); *Lucent Techs., Inc. v. Gateway, Inc*., 580 F.3d 1301, 1333 (Fed. Cir. 2009); *Monsanto Co. v. McFarling*, 488 F.3d 973, 978 (Fed. Cir. 2007); *Rite-Hite Corp. v. Kelley Co*., 56 F.3d 1538, 1545 (Fed. Cir. 1995); *Mentor Graphics Corp. v. Eve-USA, Inc.*, 870 F.3d 1298, 1299 (on Petition for Rehearing en banc 2017))(Stoll, J. concurring in denial); *Westerngeco LLC v. Ion Geophysical Corp.*,913 F.3d 1067, 1073 (2019); *State Indus., Inc. v. Mor–Flo Indus., Inc.*, 883 F.2d 1573, 1577–80 (Fed. Cir. 1989; *Ericsson, Inc. v. D-Link Sys.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014); *Garretson v. Clark*, 111 U.S. 120, 121 (1884); *Yale Lock Mfg. Co. v. Sargent*, 117 U.S. 536, 552-53 (1886); *Blake v. Robertson*, 94 U.S. 728, 729, 733-34 (1876); *Seymour v.*

McCormick, 57 U.S. (16 How.) 480, 491 (1854); *Westinghouse Electric & Manufacturing Co. v. Wagner Electric & Manufacturing Co.*, 225 U.S. 604, 614-15 (1912).

7.3 [**AMGEN'S PROPOSAL:** ATTRIBUTION/APPORTIONMENT

The amount you find as damages must be based on the value attributable to the patented methods, as distinct from other, unpatented features, such as the product itself, marketing or advertising, or the manufacturer's size or market position. Genentech must separately calculate, that is apportion, the amount of its money damages between that which is attributable to use of the patented methods and that which is attributable to the unpatented features. Calculating damages may involve estimating the value of a feature that may not have ever been individually sold. The evidence provided by Genentech for this apportionment must be reliable and tangible, and not hypothetical or speculative.

Alternately, in order to establish that Genentech's lost profits and damages should be calculated on the entire value of Herceptin, Genentech must show, by equally reliable evidence, that the either entire value of Herceptin is attributable to administering trastuzumab using the methods of the Dosing Patents, or that the entire value of Herceptin is attributable to manufacturing trastuzumab using method of the Kao Manufacturing Patent.

If you award lost profits or price erosion damages, the amount of lost profits or price erosion damages awarded must be tied to Genentech's profits attributable to its patented methods, and must not include profits attributable to other aspects of Herceptin. The lost profits damages must be limited to that portion of Genentech's

lost profits actually attributable to Amgen's direct or induced infringement of Genentech's patented methods.

If you award a reasonable royalty on Amgen's sales of Kanjinti, in determining the appropriate royalty base (that is, the amount of sales to which the royalty rate applies), and the appropriate royalty rate, the ultimate combination of both the royalty rate and the royalty base must reflect the value attributable to the patented methods. In other words, the royalty base must be closely tied to the claimed invention. It is not sufficient to use a royalty base that is too high and then adjust the damages downward by applying a lower royalty rate. Similarly, it is not appropriate to select a royalty base that is too low and then adjust it upward by applying a higher royalty rate. Rather, you must determine an appropriate base and an appropriate royalty rate that reflect the value attributable to the patented methods alone.]

[**GENENTECH'S PROPOSAL:** Section 7.16 contains Genentech's proposed instruction on attribution/apportionment.]

Authority:

AIPLA Model Jury Instructions 10.2.5.4; *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1241 (Fed. Cir. 2017); *Paper Converting Mach. Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 23 (Fed. Cir. 1984); *King Instrument Corp.*

v. Otari Corp., 767 F.2d 853, 864 (Fed. Cir. 1985); *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1578 (Fed. Cir. 1989); *Micro Chem., Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1122 (Fed. Cir. 2003); *Mentor Graphics v. EVE*, 851 F.3d 1275, 1287-88 (Fed. Cir. 2017); *Exmark Mfg. Co., v. Briggs & Stratton Power Group*, 879 F.3d 1332 (Fed. Cir. 2018): *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1339 (Fed. Cir. 2015); *Ericsson, Inc. v. D-Link Sys.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014); *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1319 (Fed. Cir. 2014); *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308 (Fed. Cir. 2014); *Versata Software, Inc. v. SAP Am., Inc.*, 717 F.3d 1255 (Fed. Cir. 2013); *LaserDynamics, Inc. v. Quanta Computer, Inc. et al*, 694 F.3d 51, 60 (Fed. Cir. 2012); *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1317 (Fed. Cir. 2011); *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 869 (Fed. Cir. 2010); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1336 (Fed. Cir. 2009); *Imonex Svcs. Inc. v. W.H. Munzprufer Dietmar Trenner GMBH*, 408 F.3d 1374 (Fed. Cir. 2005); *WesternGeco L.L.C. v. ION Geophysical Corp.*, 913 F.3d 1067, 1073-1075 (Fed. Cir. 2019); *Garretson v. Clark*, 111 U.S. 120, 121 (1884); *Yale Lock Mfg. Co. v. Sargent*, 117 U.S. 536, 552-53 (1886); *Blake v. Robertson*, 94 U.S. 728, 729, 733-34 (1876); *Seymour v. McCormick*, 57 U.S. (16 How.) 480, 491 (1854); *Westinghouse Electric & Manufacturing Co. v. Wagner Electric & Manufacturing Co.*, 225 U.S. 604, 614-15 (1912).

7.4 LOST PROFITS – "BUT- FOR" TEST

Genentech is seeking lost profits damages in this case. To prove lost profits, Genentech must show that, but for Amgen's infringement, Genentech would have made additional profits by selling Herceptin in the place of all or a portion of the sales of Kanjinti made by Amgen. Genentech must prove this by a preponderance of the evidence, more likely than not. Part of your job is to determine what the parties who purchased Kanjinti from Amgen would have done if the infringement had not occurred. [**GENENTECH'S PROPOSAL:** It is important to remember that the profits I have been referring to are the profits allegedly lost by Genentech, not the profits, if any, made by Amgen on the allegedly infringing sales.] [**AMGEN'S PROPOSAL:** It is important to remember that the profits I have been referring to are the profits allegedly lost by Genentech to Amgen's alleged infringement of the patented methods, not the profits Genentech may have lost to sales of competing trastuzumab biosimilars after December 1, 2019, and not the profits, if any, attributable to non-patented uses or features of Genentech's products. Lost profits are not the profits made by Amgen as a result of its alleged infringement of Genentech's patented methods.]

Authority:

AIPLA Model Jury Instruction 10.2.1.1; 35 U.S.C. § 284; *Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269, 1289 (Fed. Cir. 2011); *Am. Seating Co. v. USSC Grp., Inc.*, 514 F.3d 1262 (Fed. Cir. 2008); *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 507 (1964); *Micro Chem., Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1122-25 (Fed. Cir. 2003); *Ferguson Beauregard/Logic Controls v. Mega Sys., L.L.C.*, 350 F.3d 1327, 1345-46 (Fed. Cir. 2003); *Ericsson, Inc. v. Harris Corp.*, 352 F.3d 1369, 1377 (Fed. Cir. 2003); *Tate Access Floors, Inc. v. Maxcess Techs., Inc.*, 222 F.3d 958, 971 (Fed. Cir. 2000); *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999); *King Instruments Corp. v. Perego*, 65 F.3d 941, 952 (Fed. Cir. 1995); *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1577 (Fed. Cir. 1989); *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 1428 (Fed. Cir. 1988); *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 863-64 (Fed. Cir. 1985); *Paper Converting Mach. Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 21 (Fed. Cir. 1984); *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1365 (Fed. Cir. 1984); *Central Soya Co. v. Geo. A. Hormel & Co.*, 723 F.2d 1573, 1578-79 (Fed. Cir. 1983); *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1241 (Fed. Cir. 2017); *Paper Converting Mach. Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 23 (Fed. Cir. 1984); *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 864 (Fed. Cir. 1985); *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1578

(Fed. Cir. 1989); *Micro Chem., Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1122 (Fed. Cir. 2003); *Mentor Graphics Corp. v. Eve-USA, Inc.*, 870 F.3d 1298, 1299 (on Petition for Rehearing en banc 2017))(Stoll, J. concurring in denial); *Westerngeco LLC v. Ion Geophysical Corp.*,913 F.3d 1067, 1073 (2019); *Ericsson, Inc. v. D-Link Sys.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014); *Garretson v. Clark*, 111 U.S. 120, 121 (1884) *Yale Lock Mfg. Co. v. Sargent*, 117 U.S. 536, 552-53 (1886); *Blake v. Robertson*, 94 U.S. 728, 729, 733-34 (1876); *Seymour v. McCormick*, 57 U.S. (16 How.) 480, 491 (1854); *Westinghouse Electric & Manufacturing Co. v. Wagner Electric & Manufacturing Co.*, 225 U.S. 604, 614-15 (1912).

7.5 LOST PROFITS–FACTORS

Genentech is entitled to lost profits [**AMGEN'S PROPOSAL:** only] if you find that Genentech has proven each of the following factors by a preponderance of the evidence, the more likely than not standard.

1. Demand for the patented method;
2. absence of acceptable non-infringing alternatives;
3. that Genentech had the manufacturing and marketing ability to make all or a part of the infringing sales actually made by Amgen; and
4. the amount of profit that Genentech would have made if it were not for Amgen's infringement.

[**AMGEN'S PROPOSAL:** for Genentech to recover lost profits based on the Herceptin product for Amgen's alleged inducement of others to infringe the Dosing Patents, Genentech must prove that the patented method of dosing at 8 mg/kg initially followed by 6 mg/kg every three weeks (i) drove customer demand for Kanjinti, (ii) that customers would not have purchased Kanjinti if it were only available for use in accordance with non-infringing methods of administration, (iii) that Genentech possessed the marketing and manufacturing ability to satisfy all market demand for trastuzumab, and (iv) that Genentech carried its burden of proving the actual amount of its lost profits that was attributable to Amgen's inducement of others to infringe the Dosing Patents.

Similarly, for Genentech to recover lost profits of the Herceptin product for Amgen's alleged infringement of the Kao Manufacturing Patent, Genentech must prove that the patented method for preventing reduction of disulfide bonds during manufacturing (i) drove customer demand for Kanjinti, (ii) that customers would not have purchased Kanjinti if it were manufactured with a non-infringing method, (iii) that Genentech possessed the marketing and manufacturing ability to satisfy all market demand for trastuzumab, and (iv) that Genentech carried its burden of proving the actual amount of its lost profits that were attributable to Amgen's infringement of the Kao Manufacturing Patent.

If you find that Genentech has proven each of these requirements, you must additionally decide (i) whether Genentech has proven the extent of use of its patented methods, and limited its claims to lost profits that were actually caused by Amgen's use of Genentech's patented methods, as opposed to other reasons, and (ii) whether Genentech has adequately apportioned the profits it made on sales of its products to isolate profits attributable to its patented methods from profits attributable to non-patented components of Genentech's products.]

I will now explain each of these factors.

Authority:

AIPLA Model Jury Instructions 10.2.1.2; *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1241 (Fed. Cir. 2017); *Paper Converting Mach. Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 23 (Fed. Cir. 1984); *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 864 (Fed. Cir. 1985); *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1578 (Fed. Cir. 1989); *Micro Chem., Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1122 (Fed. Cir. 2003); *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275 (Fed. Cir. 2017); *Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269, 1287 (Fed. Cir. 2011); *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1329 (Fed. Cir. 2009); *Tate Access Floors, Inc. v. Maxcess Techs., Inc.*, 222 F.3d 958, 971 (Fed. Cir. 2000); *Gargoyles, Inc. v. United States*, 113 F.3d 1572, 1577-79 (Fed. Cir. 1997); *Stryker Corp. v. Intermedics Orthopedics, Inc.*, 96 F.3d 1409, 1417-18 (Fed. Cir. 1996); *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995); *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1577 (Fed. Cir. 1989); *Yarway Corp. v. Eur-Control USA, Inc.*, 775 F.2d 268, 275 (Fed. Cir. 1985); *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978).

7.6 LOST PROFITS– DEMAND

The first factor asks whether there was demand for the patented method in the relevant market. Genentech can prove demand for the patented methods by showing significant sales of Herceptin that are covered by one or more of the Asserted Patent Claims. Genentech also can prove demand for patented methods by showing significant sales of Kanjinti that are covered by one or more of the Asserted Patent Claims. To use sales of the Kanjinti as proof of this demand, however, Herceptin and Kanjinti must be sufficiently similar to compete against each other in the same market.

Authority:

AIPLA Model Jury Instructions 10.2.1.3; *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1330 (Fed. Cir. 2009); *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1548-49 (Fed. Cir. 1995); *BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc.*, 1 F.3d 1214, 1218-19 (Fed. Cir. 1993); *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 926 F.2d 1161, 1165 n.3 (Fed. Cir. 1991); *Gyromat Corp. v. Champion Spark Plug Co.*, 735 F.2d 549, 552 (Fed. Cir. 1984); *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1241 (Fed. Cir. 2017); *Paper Converting Mach. Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 23 (Fed. Cir. 1984); *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 864 (Fed. Cir. 1985);

State Indus., Inc. v. Mor-Flo Indus., Inc., 883 F.2d 1573, 1578 (Fed. Cir. 1989);

Micro Chem., Inc. v. Lextron, Inc., 318 F.3d 1119, 1122 (Fed. Cir. 2003).

7.7 LOST PROFITS—ACCEPTABLE NON-INFRINGING SUBSTITUTES

The second factor asks whether there were non-infringing, acceptable alternatives for Genentech's patented methods that competed with infringing sales of Kanjinti in the marketplace and the impact of such substitutes on the marketplace absent infringing sales of Kanjinti. If the realities of the marketplace are that competitors other than Genentech would likely have captured some or all of the infringing sales made by Amgen, even despite a difference in the methods of manufacturing or methods of administration of the competitor's product, then Genentech is not entitled to lost profits on those sales.

To be an acceptable alternative, the alternative must have one or more of the advantages of the patented invention that were important to the actual buyers of infringing sales of Kanjinti, not the public in general. To be an acceptable substitute, an alternative also must not infringe the Asserted Patent Claims, which can be because it was licensed under the patent or did not include all the features required by the Asserted Patent Claims. [**AMGEN'S PROPOSAL:** A non-infringing substitute may be one that involved modification of the method of manufacture or method of administering Kanjinti to avoid infringement, or the removal of at least one feature of the Asserted Patent Claims from the process of manufacturing Kanjinti or method of administering Kanjinti.] An acceptable alternative substitute, in addition to being either licensed or non-infringing, must

have been available during the damages period. The acceptable substitute need not have actually been sold or in use at that time. But, if the acceptable alternative was not sold during the damages period, then Amgen must show by a preponderance of the evidence that, during the damages period, Amgen had the ability to implement the acceptable substitute during the damages period. If you determine that some of the purchasers of infringing sales of Kanjinti would just as likely have purchased an acceptable non-infringing substitute, then Genentech has not shown it lost those sales but for the infringing sales of Kanjinti.

[**AMGEN'S PROPOSAL:** Even if you find that Genentech's and Amgen's products were the only ones with the advantages of the patented invention, Genentech is nonetheless required to prove to you that it, in fact, would have made the infringing sales of Kanjinti.]

Authority:

AIPLA Model Jury Instructions 10.2.1.4; *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1241 (Fed. Cir. 2017); *Paper Converting Mach. Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 23 (Fed. Cir. 1984); *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 864 (Fed. Cir. 1985); *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1578 (Fed. Cir. 1989); *Micro Chem., Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1122 (Fed. Cir. 2003); *Mentor Graphics v. EVE*, 851 F.3d

1275, 1286 (Fed. Cir. 2017); *SynQor, Inc. v. Aresyn Techs., Inc.*, 709 F.3d 1365, 1383 (Fed. Cir. 2013); *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1331-32 (Fed. Cir. 2009); *Am. Seating Co. v. USSC Grp., Inc.*, 514 F.3d 1262, (Fed. Cir. 2008); *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1372-73 (Fed. Cir. 2008); *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999); *Gargoyles, Inc. v. United States*, 113 F.3d 1572, 1577-78 (Fed. Cir. 1997); *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 939 F.2d 1540, 1545-46 (Fed. Cir. 1991); *Standard Havens Prods., Inc. v. Gencor Indus.*, 953 F.2d 1360, 1373 (Fed. Cir. 1991); *Kaufman Co. v. Lantech, Inc.*, 926 F.2d 1136, 1142-43, 1143 n.17 (Fed. Cir. 1991); *SmithKline Diagnostics, Inc. v. Helena Lab. Corp.*, 926 F.2d 1161, 1166 (Fed. Cir. 1991); *TWM Mfg. Co. v. Dura Corp.*, 789 F.2d 895, 901-02 (Fed. Cir. 1986); *Cent. Soya Co. v. Geo. A. Hormel & Co.*, 723 F.2d 1573, 1579 (Fed. Cir. 1983); *Ericsson, Inc. v. Harris Corp.*, 352 F.3d 1369, 1377 (Fed. Cir. 2003); *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 805 F.3d 1368, 1380 (Fed. Cir. 2015).

7.8 LOST PROFITS– MARKET SHARE

[**GENENTECH'S PROPOSAL:** If you find that there were acceptable non-infringing substitutes in the market, then Genentech may be entitled to lost profits on a portion of Amgen's sales of Kanjinti. Genentech may show that it is more likely than not that Herceptin competed in the same market as Kanjinti, and that Genentech would have made a portion of the infringing sales equal to at least Genentech's share of that market but for Amgen's infringement. The burden is on Genentech to prove Genentech's share of the market in which the infringing product is sold, excluding infringing products. It is not necessary for Genentech to prove that Genentech and Amgen were the only two suppliers in the market for Genentech to demonstrate entitlement to lost profits. The burden is on Genentech, however, to show that it is more likely than not that it would have sold that portion of the infringing sales had Kanjinti never existed.]

[**AMGEN'S PROPOSAL**: If you find that there were acceptable non-infringing alternative methods of administering trastuzumab (for the Dosing Patents) or non-infringing methods to prevent reduction of disulfide bonds in the manufacture of trastuzumab (for the Kao Manufacturing Patent), you must account for them in deciding whether to award Genentech lost profits. This includes accounting for the portion of sales of Kanjinti that could be manufactured or

administered without using the patented methods, as well as portion of sales that could have been sold by the companies that Genentech has licensed under the Patents-in-Suit. The burden is on Genentech to prove by a preponderance of the evidence the extent to which its share of the market for trastuzumab would be larger than it is today if it competed against the companies it has licensed under the Patents-in-Suit and Amgen, if Amgen neither infringed the methods covered by the Patents-in-Suit nor induced others to do so.

For the Kao Manufacturing Patent, this means that Genentech must show, but for Amgen's use of the method of manufacture of the Asserted Claims of the Kao Manufacturing Patent, the extent to which Genentech would have a larger share of the market for trastuzumab if it competed against the companies it has licensed under the Patents-in-Suit and Amgen's Kanjinti manufactured using a non-infringing alternative method to prevent reduction of disulfide bonds .

For the Dosing Patents, this means that Genentech must show that, but for Amgen's inducement of physicians to administer Kanjinti according to the Asserted Claims of the Dosing Patents, the extent to which Genentech would have a larger share of the market for trastuzumab if it competed against the companies it

has licensed under the Patents-in-Suit and Amgen's Kanjinti for use with non-infringing alternative methods of administering trastuzumab.[17]

In making this determination, you must separately consider whether Genentech has proven its entitlement to any lost profits for the period of time when only Amgen was in the market (before December 1, 2019), and for the period of time after the companies that Genentech has licensed under the Patents-in-Suit began competing in the market with Genentech and Amgen (after December 1, 2019), and factor out of your analysis any profits that Genentech lost as a result of competition from its licensees.]

Authority:

AIPLA Model Jury Instructions 10.2.1.5; Federal Circuit Model Patent Jury Instructions § 6.2 (2016) at 67; *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1330 (Fed. Cir. 2009); *Ericsson, Inc. v. Harris Corp.*, 352 F.3d 1369, 1377-78 (Fed. Cir. 2003); *Crystal Semiconductor Corp. v. Tritech Microelecs. Int'l, Inc.*, 246 F.3d 1336, 1353-57 (Fed. Cir. 2001); *BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc.*, 1 F.3d 1214 (Fed. Cir. 1993); *State Indus.*,

[17] Amgen will explain the significance of its use of grey shading in its supplemental briefing on jury instructions.

Inc. v. Mor-Flo Indus., Inc., 883 F.2d 1573, 1577-78 (Fed. Cir. 1989); *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1241 (Fed. Cir. 2017); *Paper Converting Mach. Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 23 (Fed. Cir. 1984); *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 864 (Fed. Cir. 1985); *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1578 (Fed. Cir. 1989); *Micro Chem., Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1122 (Fed. Cir. 2003).

7.9 LOST PROFITS– CAPACITY

The third factor asks whether Genentech had the manufacturing and marketing ability to actually make the sales it allegedly lost due to Amgen's infringement. Genentech must prove that it could have supplied the additional amount of Herceptin needed to make the sales Genentech said it lost. Genentech also must prove that it more likely than not had the ability to market and sell the additional amount of Herceptin.

Authority:

AIPLA Model Jury Instructions 10.2.1.6; *Wechsler v. Macke Int'l Trade, Inc.*, 486 F.3d 1286, 1293 (Fed. Cir. 2007); *Gargoyles, Inc. v. United States*, 113 F.3d 1572, 1577-78 (Fed. Cir. 1997); *Fonar Corp. v. Gen. Elec. Co.*, 107 F.3d 1543, 1553 (Fed. Cir. 1997); *Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1551 (Fed. Cir. 1994); *Datascope Corp. v. SMEC, Inc.*, 879 F.2d 820, 825 (Fed. Cir. 1989); *Gyromat Corp. v. Champion Spark Plug Co.*, 735 F.2d 549, 554 (Fed. Cir. 1984).

7.10 LOST PROFIT – AMOUNT OF PROFIT

Genentech may calculate the amount of its lost profits by calculating its lost sales and subtracting from that amount any additional costs or expenses that Genentech would have had to pay to make the lost sales. This might include additional costs for making the products, additional sales costs, additional packaging costs, additional shipping costs, etc. Any costs that do not change when more products are made, such as taxes, insurance, rent, and administrative overhead, should not be subtracted from the lost sales amount. The amount of lost profits cannot be speculative, but it need not be proven with unerring certainty.

[**AMGEN'S PROPOSAL**: To the extent you find that Amgen has induced infringement of the Dosing Patents, Genentech may receive damages only for sales that led to an act of direct infringement. In order to establish the amount of its lost profits, Genentech must show the connection between a sale of Kanjinti for which Genentech claims it has lost profits and Amgen's induced infringement that led to direct infringement of its Dosing Patents.

Additionally, for each sale for which Genentech claims lost profits based on induced infringement, Genentech must show by a preponderance of the evidence that Amgen's inducement of patent infringement, and not other factors such as Genentech's drug label or treatment guidelines published by others, caused the third party to directly infringe the Dosing Patents.

Genentech's lost profits damages award must further be limited to that portion of the lost profits of Herceptin actually attributable to the patented method of dosing at 8 mg/kg initially followed by 6 mg/kg every three weeks and/or the method of preventing disulfide bond reduction during manufacture. You must undertake this analysis separately for the time period before other competing biosimilar trastuzumab products were available on the market (before December 1, 2019) and the time period after other competing biosimilar trastuzumab products were available on the market (after December 1, 2019).

Even if you find that Amgen both directly infringed the Kao Manufacturing Patent and induced others to infringe one or more of the Dosing Patents, if you conclude that Genentech is entitled to lost profits on the entire sale of Herceptin, you can award Genentech the lost profits only once on each sale of Herceptin to a particular customer.

If you find that Genentech has not met its burden to demonstrate by a preponderance of the evidence the amount of profits lost due to Amgen's direct or induced infringement, you may not award lost profits.]

Authority:

AIPLA Model Jury Instructions 10.2.1.7; *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1572 (Fed. Cir. 1996); *Oiness v. Walgreen Co.*, 88 F.3d 1025, 1030

(Fed. Cir. 1996); *Beatrice Foods Co. v. New England Printing & Lithographing Co.*, 923 F.2d 1576, 1579 (Fed. Cir. 1991); *Kalman v. Berlyn Corp.*, 914 F.2d 1473, 1482-83 (Fed. Cir. 1990); *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1579-80 (Fed. Cir. 1989); *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 1428 (Fed. Cir. 1988); *Del Mar Avionics, Inc. v. Quinton Instrument Co.*, 836 F.2d 1320, 1327 (Fed. Cir. 1987); *King Instrument Corp. v. Otari*, 767 F.2d 853, 863-64 (Fed. Cir. 1985); *Gyromat Corp. v. Champion Spark Plug Co.*, 735 F.2d 549, 554-55 (Fed. Cir. 1984); *Paper Converting Mach. Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 22 (Fed. Cir. 1984); *Bio-Rad Labs., Inc. v. Nicolet Inst. Corp.*, 739 F.2d 604 (Fed. Cir. 1984); *Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1065 (Fed. Cir. 1983); *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1241 (Fed. Cir. 2017); *Paper Converting Mach. Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 23 (Fed. Cir. 1984); *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 864 (Fed. Cir. 1985); *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1578 (Fed. Cir. 1989); *Micro Chem., Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1122 (Fed. Cir. 2003); *Mentor Graphics Corp. v. Eve-USA, Inc.*, 870 F.3d 1298, 1299 (on Petition for Rehearing en banc 2017))(Stoll, J. concurring in denial); *Westerngeco LLC v. Ion Geophysical Corp.*,913 F.3d 1067, 1073 (2019); *Ericsson, Inc. v. D-Link Sys.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014); *Garretson v. Clark*, 111 U.S. 120, 121 (1884); *Yale Lock Mfg. Co. v. Sargent*, 117 U.S. 536,

552-53 (1886); *Blake v. Robertson*, 94 U.S. 728, 729, 733-34 (1876); *Seymour v. McCormick*, 57 U.S. (16 How.) 480, 491 (1854); *Westinghouse Electric & Manufacturing Co. v. Wagner Electric & Manufacturing Co.*, 225 U.S. 604, 614-15 (1912).

7.11 PRICE EROSION

Genentech is entitled to recover additional damages if it can show that it is more likely than not that, but for Amgen's infringement, Genentech would have charged higher prices for its products during the damages period.

[**AMGEN'S PROPOSAL:** Genentech must prove that it lowered its prices, or did not raise them, because of the induced or direct infringement by Amgen, and not for some other reason. Specifically, if Genentech would have lowered its prices in response to Amgen's sales of Kanjinti for non-infringing uses or in response to Amgen's sales of Kanjinti that did not use or include on the label the patented methods, or for any other reason, that reduction in price cannot be considered in assessing price erosion damages. Additionally, if after December 1, 2019, Genentech would have lowered its price in response to sales of biosimilar trastuzumab by licensed third-party competitors, that reduction in price also cannot be considered in assessing price erosion damages.]

If you find that Genentech has met its burden of proof, then you may award as additional damages an amount equal to the difference between the profits that Genentech would have made at the higher price and the profits Genentech actually

made selling its products at the lower price that Genentech charged. This type of damage is referred to as "price erosion damages."

If you find that Genentech suffered price erosion damages, then you also may use the higher price that Genentech would have charged in determining Genentech's lost sales and lost profits due to Amgen's infringement. However, if you calculate price erosion damages using the higher price for Genentech's product, then you also must take into account any decrease in Genentech's sales that might have occurred due to the higher price for the products.

Authority:

AIPLA Model Jury Instructions 10.2.2; *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 711 F.3d 1348, 1377-80 (Fed. Cir. 2013); *Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269, 1287 (Fed. Cir. 2011); *Ericsson, Inc. v. Harris Corp.*, 352 F.3d 1369, 1378-79 (Fed. Cir. 2003); *Vulcan Eng'g Co. v. FATA Aluminum, Inc.*, 278 F.3d 1366, 1377 (Fed. Cir. 2002); *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1544 (Fed. Cir. 1995) (en banc) (applying test articulated in *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978)); *BIC Leisure, Inc. v. Windsurfing Int'l, Inc.*, 1 F.3d 1214, 1218 (Fed. Cir. 1993); *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1578-79 (Fed. Cir. 1992); *Amstar*

Corp. v. Envirotech Corp., 823 F.2d 1538, 1543 (Fed. Cir. 1987); *Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1065 (Fed. Cir. 1983).

7.12 COST ESCALATION

Genentech can recover additional damages if it can show that it also lost profits because its costs—such as additional marketing costs—went up as a result of Amgen's infringement of Genentech's patents. Genentech must prove that it was more likely than not that its costs went up because of Amgen's actions, and not for some other reason.

Authority:

2018 AIPLA Model Patent Jury Instructions, No. 10.2.3; *Amstar Corp. v. Envirotech Corp.*, 823 F.2d 1538, 1543 (Fed. Cir. 1987); *Lam, Inc. v. JohnsManville Corp.*, 718 F.2d 1056, 1064-65 (Fed. Cir. 1983).

7.13 REASONABLE ROYALTY – GENERALLY

If you find that Genentech has not proven its claim for lost profits, or if you find that Genentech has proven its claim for lost profits for only a portion of the infringing sales, then you must consider the issue of a reasonable royalty.

The amount of damages that Amgen pays Genentech for infringing the Asserted Patent Claims must be enough to compensate for the infringement, but may not be less than a reasonable royalty for the use of Genentech's inventions.

You must award Genentech a reasonable royalty in the amount that Genentech has proven it could have earned for any infringing sales for which you have not already awarded lost profit damages. A royalty is a payment made by someone else in exchange for the rights to make, use, sell or import a patented invention.

The reasonable royalty award must be based on the incremental value that the patented method adds to the end product. When the product sold has both patented and unpatented features or is used or made in both patented and unpatented ways, measuring this value requires a determination of the value added by the patented features or uses.

One way to calculate a royalty is to determine what is called an "ongoing royalty" or "running royalty." To calculate an ongoing royalty, you must first determine the "base," that is, the product or uses on which the infringer is to pay

the royalty. You then need to multiply the revenue the infringing party obtained from the base by the "rate" or percentage that you find would have resulted from the hypothetical negotiation. The ultimate combination of royalty base and royalty rate must reflect the value attributable to the infringing features or uses, and no more.

Another way to calculate a royalty is to determine a one-time lump sum payment that the alleged infringer would have paid at the time of the hypothetical negotiation for a license covering all sales of the product to be covered by the license, both past and future. This differs from payment of an ongoing royalty because, with an ongoing royalty, the licensee pays based on the revenue of actual licensed products it sells. When a one-time lump sum is paid, the alleged infringer pays a single price for a license covering both past and future infringing sales to be covered by the license. It is up to you, based on the evidence, to decide what type of royalty is appropriate in this case.

Authority:

AIPLA Model Jury Instructions 10.2.5.1; 35 U.S.C. § 284; *Exmark Mfg. Co., v. Briggs & Stratton Power Group*, 879 F.3d 1332 (Fed. Cir. 2018); *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014); *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1326 (Fed. Cir. 2014); *Apple Inc. v. Motorola Inc.*, 757 F.3d

1286 (Fed. Cir. 2014); *Uniloc USA, Inc. v. Microsoft Corp*., 632 F.3d 1292, 1312 (Fed. Cir. 2011); *Lucent Techs., Inc. v. Gateway, Inc*., 580 F.3d 1301, 1324-25 (Fed. Cir. 2009); *Fromson v. W. Litho Plate & Supply Co*., 853 F.2d 1568, 1574 (Fed. Cir. 1998) *overruled on other grounds; Knorr-Bremse Systeme Fuer Nutzfahrzeuge v. Dana Corp.*, 383 F.3d 1337, 1342 (Fed. Cir 2004); *Minco, Inc. v. Combustion Eng'g, Inc*., 95 F.3d 1109, 1119 (Fed. Cir. 1996); *Mahurkar v. C.R. Bard, Inc*., 79 F.3d 1572, 1579 (Fed. Cir. 1996); *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1554 (Fed. Cir. 1995) (en banc).

7.14 REASONABLE ROYALTY—HYPOTHETICAL NEGOTIATION

A reasonable royalty is the royalty that would have resulted from a hypothetical license negotiation between Genentech and Amgen. Of course, we know that they did not agree to a license and royalty payment. But, in order to decide on the amount of reasonable royalty damages, you should assume that the parties did negotiate a license just before any infringement began. This is why it is called a "hypothetical" license negotiation. You should assume that both parties to the hypothetical negotiation understood that the patent was valid and infringed and both were willing to enter into a license just before the infringement began. You should also presume that the parties had full knowledge of the facts and circumstances surrounding the alleged infringement at the time of the hypothetical negotiation.

Authority:

AIPLA Model Jury Instructions 10.2.5.2; *Apple Inc. v. Motorola Inc.*, 757 F.3d 1286 (Fed. Cir. 2014); *LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 75 (Fed. Cir. 2012); *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1311 (Fed. Cir. 2011); *Fujifilm Corp. v. Benun*, 605 F.3d 1366, 1372 (Fed. Cir. 2010); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324-25 (Fed. Cir. 2009); *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1579 (Fed. Cir. 1996); *Maxwell v. J.*

Baker, Inc., 86 F.3d 1098, 1109-10 (Fed. Cir. 1996); *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1554 (Fed. Cir. 1995) (en banc); *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 870 (Fed. Cir. 1993).

7.15 REASONABLE ROYALTY – FACTORS

In determining the amount of a reasonable royalty, you may consider evidence on any of the following factors, in addition to any other evidence presented by the parties on the economic value of the patent:

1. Any royalties received by the Genentech for the licensing of the Asserted Patents, proving or tending to prove an established royalty.

2. The rates paid by Amgen to license other patents comparable to the Asserted Patents.

3. The nature and scope of the license, as exclusive or non-exclusive, or as restricted or non-restricted in terms of its territory or with respect to whom the manufactured product may be sold.

4. Genentech's established policy and marketing program to maintain its right to exclude others from using the patented invention by not licensing others to use the invention, or by granting licenses under special conditions designed to preserve that exclusivity.

5. The commercial relationship between the Genentech and Amgen, such as whether or not they are competitors in the same territory in the same line of business.

6. The effect of selling the patented method in promoting other sales of the licensee; the existing value of the invention to the licensor as a generator of sales of its non-patented items; and the extent of such collateral sales.

7. The duration of the Asserted Patents and the term of the license.

8. The established profitability of the product made under the Asserted Patents; its commercial success; and its popularity.

9. The utility and advantages of the patented invention over the old modes or devices, if any, that had been used for achieving similar results.

10. The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by or for the licensor; and the benefits to those who have used the invention.

11. The extent to which Amgen has made use of the invention; and any evidence that shows the value of that use.

12. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.

13. The portion of the profit that arises from the patented invention itself as opposed to profit arising from unpatented features, such as the manufacturing process, business risks, or significant features or improvements added by the accused infringer.

14. The opinion testimony of qualified experts.

15. The amount that a licensor (such as Genentech) and a licensee (such as Amgen) would have agreed upon (at the time the infringement began) if both sides had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee—who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention—would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a patentee who was willing to grant a license.

16. Any other economic factor that a normally prudent business person would, under similar circumstances, take into consideration in negotiating the hypothetical license.

Authority:

AIPLA Model Jury Instructions 10.2.5.3; *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1230-32 (Fed. Cir. 2014); *Apple Inc. v. Motorola Inc.*, 757 F.3d 1286 (Fed. Cir. 2014); *LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 60

(Fed. Cir. 2012); *Wordtech Sys., Inc. v. Integrated Networks Solutions, Inc.*, 609 F.3d 1308, 1319 (Fed. Cir. 2010); *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 869-73 (Fed. Cir. 2010); *Monsanto Co. v. McFarling,* 488 F.3d 973 (Fed. Cir. 2007); *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1108-10 (Fed. Cir. 1996); *TWM Mfg. Co. v. Dura Corp.*, 789 F.2d 895, 898-900 (Fed. Cir. 1986); *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116 (S.D.N.Y. 1970).

7.16 [**GENENTECH'S PROPOSAL:** REASONABLE ROYALTY– ATTRIBUTION/APPORTIONMENT

The amount you find as damages must be based on the value attributable the patented technology, as distinct from other, unpatented features or other factors such as marketing or advertising, or Amgen's size or market position. You must determine an appropriate reasonable royalty that reflects the value attributable to the patented invention alone.]

[**AMGEN'S PROPOSAL:** Section 7.3 contains Amgen's proposed instruction on attribution/apportionment.]

Authority:

AIPLA Model Jury Instructions 10.2.5.4; *Exmark Mfg. Co., v. Briggs & Stratton Power Group,* 879 F.3d 1332 (Fed. Cir. 2018): *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1339 (Fed. Cir. 2015); *Ericsson, Inc. v. D-Link Sys.*, 773 F.3d

1201, 1226 (Fed. Cir. 2014); *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1319 (Fed. Cir. 2014); *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308 (Fed. Cir. 2014); *Versata Software, Inc. v. SAP Am., Inc.*, 717 F.3d 1255 (Fed. Cir. 2013); *LaserDynamics, Inc. v. Quanta Computer, Inc. et al*, 694 F.3d 51, 60 (Fed. Cir. 2012); *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1317 (Fed. Cir. 2011); *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 869 (Fed. Cir. 2010); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1336 (Fed. Cir. 2009); *Imonex Svcs. Inc. v. W.H. Munzprufer Dietmar Trenner GMBH*, 408 F.3d 1374 (Fed. Cir. 2005).

7.17

7.17 REASONABLE ROYALTY – MULTIPLE PATENTS

If you find that Amgen infringed multiple patents, even by a single infringing act, and if you award a reasonable royalty for the infringement, then you may award separate royalties to Genentech for each infringed patent. You also may consider evidence of the number of patent licenses that are needed and the effect on the hypothetical negotiation of having to pay a royalty for each of those licenses.

Authority:

2018 AIPLA Model Patent Jury Instructions, No. 10.2.5.6; *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1234 (Fed. Cir. 2014); *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1324 (Fed. Cir. 2014); *Stickle v. Heublein, Inc.*, 716 F.2d 1550, 1561 n.8 (Fed. Cir. 1983); *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1310 (Fed. Cir. 2007).

7.18 REASONABLE ROYALTY—TIMING

Damages are not based on a hindsight evaluation of what happened, but on what the parties to the hypothetical license negotiations would have agreed upon. Nevertheless, evidence relevant to the negotiation is not necessarily limited to facts that occurred on or before the date of the hypothetical negotiation. You may also consider information the parties would have foreseen or estimated during the hypothetical negotiation, which may under certain circumstances include evidence of usage after the alleged infringement started, license agreements entered into by the parties shortly after the date of the hypothetical negotiation, profits earned by the alleged infringer, and non-infringing alternatives.

Authority:

AIPLA Model Jury Instructions 10.2.5.7; 35 U.S.C. § 284; *Sinclair Ref. Co. v. Jenkins Petroleum Process Co.*, 289 U.S. 689, 698 (1933); *Aqua Shield v. Inter Pool Cover Team, et al.*, 774 F.3d 766, 770-773 (Fed. Cir. 2014); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324-25, 1333 (Fed. Cir. 2009); *Riles v. Shell Exploration & Prod. Co.*, 298 F.3d 1302, 1311 (Fed. Cir. 2002); *Interactive Pictures Corp. v. Infinite Pictures Corp.*, 274 F.3d 1371, 1384-85 (2001); *Studiengesellschaft Kohle, mbH v. Dart Indus., Inc.*, 862 F.2d 1564, 1571 (Fed. Cir. 1988); *Fromson v. Western Litho Plate & Supply Co.*, 853 F.2d 1568, 1574

(Fed. Cir. 1988); *TWM Mfg. Co. v. Dura Corp.*, 789 F.2d 895, 898-900 (Fed. Cir. 1986).

7.19 REASONABLE ROYALTY—AVAILABILITY OF NON-INFRINGING ALTERNATIVES

In determining a reasonable royalty, you may also consider evidence concerning the availability and cost of acceptable non-infringing alternatives to the patented invention. An acceptable alternative must be a method that is licensed under the patent or that does not infringe the patent.

Authority:

AIPLA Model Jury Instructions 10.2.5.8; *Prism Techs. LLC v. Sprint Spectrum L.P.*, 849 F.3d 1360, 1376-1377 (Fed. Cir. 2017); *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1313 (Fed. Cir. 2011); *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1372-73 (Fed. Cir. 2008); *Zygo Corp. v. Wyko Corp.*, 79 F.3d 1563, 1571-72 (Fed. Cir. 1996).

7.20 REASONABLE ROYALTY– USE OF COMPARABLE LICENSE AGREEMENTS

When determining a reasonable royalty, you may consider evidence concerning the amounts that other parties have paid for rights to the Asserted Patents, or for rights to similar technologies. A license agreement need not be perfectly comparable to a hypothetical license that would be negotiated between Genentech and Amgen in order for you to consider it. However, if you choose to rely upon evidence from any other license agreements, you must account for any differences between those licenses and the hypothetically negotiated license between Genentech and Amgen, in terms of the technologies and economic circumstances of the contracting parties, when you make your reasonable royalty determination.

Authority:

2018 AIPLA Model Patent Jury Instructions, No. 10.2.5.9; *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1227-28 (Fed. Cir. 2014); *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1330-31 (Fed. Cir. 2014); *Apple Inc. v. Motorola Inc.*, 757 F.3d 1286, 1325-26 (Fed. Cir. 2014); *LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 77-81 (Fed. Cir. 2012); *ResQNet.com, Inc. v. Lansa, Inc.*, 594

F.3d 860, 869-70 (Fed. Cir. 2010); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1329, 1336 (Fed. Cir. 2009).

7.21 [**GENENTECH'S PROPOSAL:** DAMAGES– DOUBTS RESOLVED AGAINST INFRINGER[18]

Any doubts that you may have on the issue of damages due to Amgen's failure to keep proper records should be decided in favor of Genentech. Any confusion or difficulties caused by Amgen's records also should be held against Amgen, not Genentech.]

Authority:

2018 AIPLA Model Patent Jury Instructions, No. 10.3; *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1572-73 (Fed. Cir. 1996); *Lam, Inc. v. JohnsManville Corp.*, 718 F.2d 1056, 1065 (Fed. Cir. 1983).

[18] Amgen objects to the inclusion of an instruction regarding doubts resolved against infringer, for the reasons Amgen will explain in its supplemental briefing on jury instructions.

8. WILLFUL INFRINGEMENT

[**GENENTECH'S PROPOSAL**: If you have decided that Amgen has infringed a valid claim of Genentech's patents, then you must go on and address the additional issue of whether or not this infringement was willful. In this case, Genentech alleges both that Amgen infringed the Asserted Patent Claims and, further, that Amgen infringed willfully. Amgen denies that its conduct was willful.]

[**AMGEN'S PROPOSAL:** In this case, Genentech alleges both that Amgen infringed and, further, that Amgen infringed willfully the Asserted Patent Claims. Amgen contends that its conduct was not willful because it had a reasonable belief that the Patents-in-Suit are invalid, not infringed, and/or unenforceable. Amgen additionally contends that its conduct was not willful in part because it relied on opinion of counsel that the Asserted Claims of the Kao Manufacturing Patent were neither valid nor infringed, and on opinion of counsel that the Asserted Claims of the Dosing Patents were invalid.

For any Asserted Patent Claim that is infringed, not invalid, and not unenforceable you must go on and address the additional issue of whether or not this infringement was willful.]

To show that Amgen's infringement was willful, Genentech must prove by a preponderance of the evidence that Amgen knew of a Patent-in-Suit and

intentionally infringed at least one Asserted Patent Claim. However, you may not find that Amgen's infringement was willful merely because Amgen knew about a Patent-in-Suit and infringed it, without more. Instead, willful infringement requires Amgen to have acted despite a risk of infringement of a valid patent claim that was either known or so obvious that it should have been known to Amgen. [**AMGEN'S PROPOSAL:** For example, in deciding whether or not Amgen knew it was infringing a patent it knew to be valid, you may consider whether Amgen's behavior was malicious, wanton, deliberate, consciously wrongful, flagrant, or in bad faith.]

To determine whether Amgen acted willfully, consider all facts. These may include, but are not limited to:

1. Whether or not Amgen acted consistently with the standards of behavior for its industry;
2. [**GENENTECH'S PROPOSAL:** Whether or not Amgen intentionally copied an invention of Genentech that is covered by the Patents-in-Suit;]
3. Whether or not Amgen reasonably believed it did not infringe or that the Asserted Patent Claims were invalid;

4. Whether or not Amgen made a good-faith effort to avoid infringing the Patents-in-Suit, for example, whether Amgen attempted to design-around the patents;
5. Whether Amgen knew, or should have known, that its conduct involved an unreasonable risk of infringement; and
6. Whether Amgen reasonably relied on a lawyer's opinion.

[**GENENTECH'S PROPOSAL**: To the extent that you consider Amgen's reliance on an opinion of its outside counsel, you must evaluate whether the opinion was of a quality that reliance on its conclusions was reasonable. Factors you may consider when determining whether Amgen reasonably relied on the legal opinion include the timing of the opinion, the nature of the advice, the thoroughness and competence of the opinion, and its objectivity.]

If you determine that any infringement was willful, you may not allow that decision to affect the amount of any damages award you give for infringement.

Authority:

AIPLA's Model Patent Jury Instructions Nos. 11.0, 11.1; 35 U.S.C. § 298; N.D. Cal. Model Patent Jury Instructions, § 3.8 (2019) at 24; Federal Circuit Bar Association Model Patent Jury Instructions § 3.10 (2016) at 37; *Orexo AB v. Actavis*, C.A. No. 1:17-cv-00205-CFC, Proposed Joint Final Instructions, D.I. 270

(D. Del. March 28, 2019) at 22-23; *F'Real Foods, LLC v. Hamilton Beach Brands, Inc.*, C.A. No. 1:16-cv-00041-CFC, D.I. 255, Proposed Final Jury Instructions (D. Del. Apr. 28, 2019) at 20-21; *Eko Brands, LLC v. Adrian Rivera Maynez Enterprises, Inc.*, 946 F.3d 1367, at *2 (Fed. Cir. 2020); *Halo Elec., Inc. v. Pulse Elec., Inc.*, 136 S.Ct. 1923, 1934 (2016); *Spectralytics, Inc. v. Cordis Corp.*, 649 F.3d 1336, 1347-48 (Fed. Cir. 2011); *Aspex Eyewear, Inc. v. Clariti Eyewear, Inc.*, 605 F.3d 1305, 1313 (Fed. Cir. 2010); *SRI Int'l, Inc. v. Advanced Tech. Labs., Inc.*, 127 F.3d 1462, 1465 (Fed. Cir. 1997); *Minnesota Min. & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1580-81 (Fed. Cir. 1992).

9. DELIBERATION AND VERDICT

9.1 INTRODUCTION

That concludes the part of my instructions explaining the rules for considering some of the testimony and evidence. Now let me finish by explaining some things about your deliberations in the jury room, and your possible verdicts.

Once you start deliberating, do not talk to the jury officer, or to me, or to anyone else except each other about the case. If you have any questions or messages, you must write them down on a piece of paper, sign them, and then give them to the jury officer. The officer will give them to me, and I will respond as soon as I can. I may have to talk to the lawyers about what you have asked, so it may take me some time to get back to you. Any question or message should be sent to me through your foreperson, who by custom of this Court is Juror No. 1.

One more thing about messages. Do not ever write down or tell anyone outside of the jury how you stand on your votes. For example, do not write down or tell anyone that you are split 4-4, or 6-2, or whatever your vote happens to be. That should stay secret until you are finished.

Authority:

F'Real Foods, LLC v. Hamilton Beach Brands, Inc., C.A. No. 1:16-cv-00041-CFC, D.I. 255, Proposed Final Jury Instructions (D. Del. Apr. 28, 2019) at 50; *Orexo AB v. Actavis Elizabeth, LLC*, C.A. No. 1:17-cv-00205-CFC, D.I. 240, Proposed Joint Final Jury Instructions (D. Del. March 28, 2019) at 30; *Amgen v. Hospira*, C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. Sept. 22, 2017) at 34; *E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No. 1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 42; *EMC Corp. v. Pure Storage, Inc.*, C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 43.

9.2 UNANIMOUS VERDICT

Your verdict must represent the considered judgment of each juror. In order for you as a jury to return a verdict, it is necessary that each juror agree to the verdict. Your verdict must be

unanimous.

It is your duty, as jurors, to consult with one another and to deliberate with a view towards reaching an agreement, if you can do so consistent with your individual judgment. Each of you must decide the case for yourself but do so only after an impartial consideration of the evidence with your fellow jurors. In the course of your deliberations, do not hesitate to reexamine your own views and change your opinion, if convinced it is erroneous. But do not surrender your honest conviction as to the weight or effect of evidence solely because of the opinion of your fellow jurors, or for the purpose of returning a verdict. Remember at all times that you are not partisans. You are judges of the facts. Your sole interest is to seek the truth from the evidence in the case.

A verdict form has been prepared for you. The verdict form asks you a series of questions about the parties' contentions. You will take this form to the jury room and when you have reached unanimous agreement as to your verdict, you will have your foreperson fill in, date, and sign the form. You will then return to the courtroom and your foreperson will give your verdict. Unless you are

directed otherwise in the verdict form, you must answer all of the questions posed, and you all must agree on each answer.

Authority:

F'Real Foods, LLC v. Hamilton Beach Brands, Inc., C.A. No. 1:16-cv-00041-CFC, D.I. 255, Proposed Final Jury Instructions (D. Del. Apr. 28, 2019) at 51; *Orexo AB v. Actavis Elizabeth, LLC*, C.A. No. 1:17-cv-00205-CFC, D.I. 240, Proposed Joint Final Jury Instructions (D. Del. March 28, 2019) at 31; *Amgen v. Hospira*, C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. Sept. 22, 2017) at 35; *AVM Tech., LLC v. Intel Corp.*, C.A. No. 15-33-RGA-MPT, D.I. 719, Final Jury Instructions (D. Del. May 8, 2017) at 28; *EMC Corp. v. Pure Storage, Inc.*, C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 44.

9.3 DUTY TO DELIBERATE

Now that all the evidence is in and the arguments are completed, you are free to talk about the case in the jury room. In fact, it is your duty to talk with each other about the evidence and to make every reasonable effort you can to reach a unanimous agreement. Talk with each other, listen carefully and respectfully to each other's views, and keep an open mind as you listen to what your fellow jurors have to say. Try your best to work out your differences. Do not hesitate to change your mind if you are convinced that other jurors are right, and your original position was wrong.

But do not ever change your mind just because other jurors see things differently, or just to get the case over with. In the end, your vote must be exactly that—your own vote. It is important for you to reach unanimous agreement, but only if you can do so honestly and in good conscience.

No one will be allowed to hear your discussions in the jury room, and no record will be made of what you say. So you should all feel free to speak your minds.

Listen carefully to what the other jurors have to say, and then decide for yourself.

Authority:

F'Real Foods, LLC v. Hamilton Beach Brands, Inc., C.A. No. 1:16-cv-00041-CFC, D.I. 255, Proposed Final Jury Instructions (D. Del. Apr. 28, 2019) at 52; *Orexo AB v. Actavis Elizabeth, LLC*, C.A. No. 1:17-cv-00205-CFC, D.I. 240, Proposed Joint Final Jury Instructions (D. Del. March 28, 2019) at 32; *Amgen v. Hospira,* C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. Sept. 22, 2017) at 36; *E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No. 1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 44; *AVM Tech., LLC v. Intel Corp.*, C.A. No. 15-33-RGA-MPT, D.I. 719, Final Jury Instructions (D. Del. May 8, 2017) at 29; *EMC Corp. v. Pure Storage, Inc*., C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 45.

9.4 SOCIAL MEDIA

During your deliberations, you must not communicate with or provide any information to anyone by any means about this case. You may not use any electronic device or media, such as the telephone, a cell phone, smart phone, iPhone, blackberry or computer, the internet, any internet service, any text or instant messaging service, any internet chat room, blog, or website such as Facebook, Instagram, Snapchat, MySpace, LinkedIn, YouTube, or Twitter, to communicate to anyone any information about this case or to conduct any research about this case until I accept your verdict. In other words, you cannot talk to anyone on the phone, correspond with anyone, or electronically communicate with anyone about this case. You can discuss the case only in the jury room with your fellow jurors during deliberations.

Authority:

Orexo AB v. Actavis Elizabeth, LLC, C.A. No. 1:17-cv-00205-CFC, D.I. 240, Proposed Joint Final Jury Instructions (D. Del. March 28, 2019) at 33; *Amgen v. Hospira,* C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. September 22, 2017) at 37; *E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No. 1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017)

at 45; *EMC Corp. v. Pure Storage, Inc.*, *C.A. No. 13-1985-RGA*, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 46.

9.5 COURT HAS NO OPINION

Let me finish up by repeating something that I said to you earlier. Nothing that I have said or done during this trial was meant to influence your decision in any way. You must decide the case yourselves based on the evidence presented.

Authority:

F'Real Foods, LLC v. Hamilton Beach Brands, Inc., C.A. No. 1:16-cv-00041-CFC, D.I. 255, Proposed Final Jury Instructions (D. Del. Apr. 28, 2019) at 53; *Orexo AB v. Actavis Elizabeth, LLC*, C.A. No. 1:17-cv-00205-CFC, D.I. 240, Proposed Joint Final Jury Instructions (D. Del. March 28, 2019) at 34; *Amgen v. Hospira,* C.A. No. 1:15-cv-839-RGA, D.I. 323, Final Jury Instructions (D. Del. Sept. 22, 2017) at 38; *E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, C.A. No. 1:14-cv-01250-RGA, D.I. 325, Final Jury Instructions (D. Del. May 15, 2017) at 46; *AVM Tech., LLC v. Intel Corp.*, C.A. No. 15-33-RGA-MPT, D.I. 719, Final Jury Instructions (D. Del. May 8, 2017) at 29; *EMC Corp. v. Pure Storage, Inc*., C.A. No. 13-1985-RGA, D.I. 448, Final Jury Instructions (D. Del. March 15, 2016) at 47.